IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A., as Trustee, Plaintiff, - against - SANOFI, Defendant.	Case No. 15 Civ. 08725 (GBD) **JURY TRIAL DEMANDED**

SECOND AMENDED COMPLAINT[1]

Plaintiff UMB Bank, N.A., as Trustee ("UMB" or the "Trustee")[2] under the Contingent Value Rights Agreement ("CVR Agreement") between Sanofi and the Trustee, dated March 30, 2011, by its undersigned attorneys, as and for its Second Amended Complaint against defendant Sanofi, alleges as follows:

NATURE OF THE ACTION

1. The CVR Agreement at issue in this action was created in connection with Defendant Sanofi's purchase of Genzyme Corporation ("Genzyme"), a biotechnology corporation in 2011.

2. When Sanofi sought to acquire it in 2010 for approximately $20 billion, Genzyme rejected Sanofi's offer as inadequate. The difference in valuation was largely attributable to two separate issues:

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[1] Plaintiff has also filed a Supplemental Complaint (ECF. No. 52) which, subject to the Court's September 8, 2016 Order (ECF No. 76), remains operative in this litigation.

[2] References to "the Trustee" in connection with events that took place before July 19, 2016, the date UMB was formally substituted as trustee under the CVR Agreement, are to American Stock Transfer & Trust Company, LLC ("AST"). A true and correct copy of the CVR Agreement is attached hereto as Exhibit A. Capitalized terms not defined herein are used as defined in the CVR Agreement.

i. the value of a promising drug, Lemtrada®, a brand name for alemtuzumab, which at the time was in Phase III clinical trials and which Genzyme thought would soon be approved by the FDA for the treatment of relapsing remitting multiple sclerosis ("MS") – Genzyme forecasted that Lemtrada® (which, unlike traditional MS treatments that require a daily or weekly dosing regime, had a unique treatment cycle of only two annual treatment courses) would be a blockbuster drug with annual sales in the billions, and was a possible cure for MS; and

ii. the value of Cerezyme® and Fabrazyme®, two highly successful biotechnology products with sales over a billion dollars per year approved for the treatment of two rare genetic diseases (Gaucher Disease (Cerezyme) and Fabry Disease (Fabrazyme)), which were the subject of production problems at the Allston, Massachusetts facility at which they were manufactured – Genzyme forecasted the production problems would be resolved, leading to increased production of both drugs.

3. In February 2011, defendant Sanofi entered into a merger agreement (the "Merger Agreement") with Genzyme. In or before April 2011, Sanofi purchased more than 90% of Genzyme's shares to effectuate the merger.

4. To bridge the valuation gap, in addition to $74 cash per share, Sanofi paid Genzyme shareholders one Contingent Value Right (the "CVR") for each share tendered. In Genzyme's Schedule 14D-9, filed with the Securities and Exchange Commission on March 7, 2011 and published to its shareholders, Genzyme estimated the value of each CVR at $5.58, as of March 2011, and recommended that its shareholders approve the merger. The CVRs were subject to the CVR Agreement between Sanofi and AST, as Trustee of an express trust for the benefit of the CVR holders (the "Holders"). The CVRs are securities, and are actively traded on

NASDAQ. UMB is successor Trustee, and acts on behalf of the Holders pursuant to the CVR Agreement, and brings this action solely in its capacity as Trustee under the CVR Agreement.

5. Pursuant to the CVR Agreement, Sanofi agreed to make up to approximately $3.8 billion in additional payments to the Holders upon the completion of certain milestones, including gaining Federal Drug Administration ("FDA") approval of Lemtrada® on or before March 31, 2014 (the "Approval Milestone"), obtaining specific Lemtrada® sales volumes in defined periods (the "Product Sales Milestones"), and reaching certain production targets for Cerezyme® and Fabrazyme® in the calendar year 2011 (the "Production Milestone").

6. In order to ensure that Sanofi would properly endeavor to meet each of the milestones, the parties agreed that Sanofi would meet certain standards of conduct. For the Lemtrada®-related milestones (the Approval Milestone and the Product Sales Milestones), the CVR Agreement imposed a standard of "Diligent Efforts" as defined therein (and defined *infra* at ¶ 30). Among other things, Diligent Efforts requires that Sanofi ignore any cost of potential milestone payments in working to gain regulatory approval and commercialize Lemtrada®. For the milestone related to the production of Cerezyme® and Fabrazyme® (the Production Milestone), the CVR Agreement imposed "commercially reasonable efforts" be employed by Sanofi "on a timely basis."

7. In addition, in order to safeguard the rights of the Holders, the CVR Agreement included significant disclosure and reimbursement obligations on Sanofi. Express contractual provisions in the CVR Agreement grant the Trustee the power to make investigative requests of Sanofi, initiate independent audits, and pursue claims for breach, all of which Sanofi is expressly required to fund.

8. To date, Sanofi has paid nothing to the Holders in connection with the

CVRs, in effect succeeding in acquiring Genzyme at a price that the Genzyme Board of Directors had determined was inadequate. Sanofi has repeatedly shirked its obligations under the CVR Agreement, resulting in multiple material breaches of the CVR Agreement, including:

a. Sanofi has failed to use Diligent Efforts with respect to Lemtrada® to achieve the Approval Milestone and the Product Sales Milestones that would have resulted in payments to the Trustee pursuant to the CVR Agreement for the benefit of Holders, and for breach of the implied covenant of good faith and fair dealing arising from Sanofi's bad faith actions.

b. Sanofi has failed to use "commercially reasonable efforts" to achieve the Production Milestone related to the production of the drugs Cerezyme® and Fabrazyme® "on a timely basis."

c. Sanofi has flatly refused to comply with multiple Trustee investigation requests, thereby breaching its obligation under Sections 4.2(f) and 5.4(b) of the CVR Agreement to allow the Trustee to "examine the books, records and premises of the Company, personally or by agent or attorney, as necessary" as requested by the Trustee "at the sole cost of [Sanofi]."

d. Sanofi has refused to cooperate with a request from the Trustee that it submit to an audit to verify the accuracy of its Product Sales Statements and underlying figures relating to Lemtrada®, thereby breaching its obligation under Section 7.6(a) of the CVR Agreement.

e. As set forth in the Supplemental Complaint (*see* footnote 1, *supra*), Sanofi has failed to meet its explicit and unqualified obligation under the CVR Agreement to pay the Trustee, upon its request or demand, its reasonable attorneys' fees,

disbursements, and expenses, and all other costs, expenses, and disbursements incurred and advances made by the Trustee, in connection with its investigation and prosecution of the claims brought in the above-captioned action.

THE PARTIES

9. Plaintiff UMB, the Trustee, is a federally-chartered national banking organization with a principal place of business in Kansas City, Missouri. UMB is a wholly-owned subsidiary of UMB Financial Corporation, a publicly-held corporation organized under Missouri law.

10. The Trustee, as trustee of an express trust for the benefit of the Holders, brings this action pursuant to Section 4.1, Section 8.1, and Section 8.2 of the CVR Agreement. UMB succeeded AST as Trustee on July 19, 2016 pursuant to Court's substitution order.

11. Defendant Sanofi is incorporated under the laws of France as a *société anonyme*, a form of limited liability company, with its principal place of business in Paris, France. Sanofi is a global pharmaceutical company engaged in the research, development, manufacturing, and marketing of healthcare products. The CVR Agreement defines an Affiliate of Sanofi, in part, as "any other Person directly or indirectly controlling or controlled by or under direct or indirect common control with such specified Person." Genzyme, a wholly owned subsidiary of Sanofi, is an Affiliate of Sanofi.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332 and the amount in controversy, without interest and costs, exceeds the sum or value specified therein.

13. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2).

14. Pursuant to Section 1.10 of the CVR Agreement, Sanofi has agreed to submit to the exclusive jurisdiction and venue of the United States District Court for the Southern District of New York.

15. As specified under Section 8.1(b) of the CVR Agreement, the Trustee gave written notice to Sanofi by certified mail that Sanofi had breached the CVR Agreement and requesting Sanofi to remedy the material breaches identified therein (the "Notice of Breach"). Sanofi received the Notice of Breach on or before August 7, 2015. At least 90 days have passed since Sanofi was given Notice of Breach, and Sanofi's breaches have not been cured and are continuing.

THE FACTS

16. Under the CVR Agreement, Sanofi agreed to make payments to the Trustee, as trustee of an express trust for the benefit of the Holders, upon the occurrence of certain milestones related to the regulatory approval and sales volume of Genzyme's multiple sclerosis drug Lemtrada®. These milestones are described in the CVR Agreement as the Approval Milestone and the Product Sales Milestones.

17. Under the CVR Agreement, the parties agreed that Sanofi would use "Diligent Efforts" to achieve the Approval Milestone and the Product Sales Milestones. Diligent Efforts include causing Genzyme to take certain actions to enable the achievement of those milestones and require that Sanofi not take into account the payments to the Trustee, on behalf of the Holders, under the CVR Agreement when assessing the profitability of Lemtrada®.

18. Sanofi materially breached the CVR Agreement by, among other things, failing to use Diligent Efforts to achieve the Approval Milestone and the Product Sales Milestones, not one of which has been achieved. In particular:

a. Sanofi failed to cause Genzyme to follow the recommendations of the FDA and customary industry practice with respect to obtaining timely regulatory approval of Lemtrada® and failed to cause Genzyme to submit an adequate application for FDA approval of Lemtrada® that addressed the FDA's repeated concerns. As a result of its failure to use such efforts and employ such resources normally used by other companies in the pharmaceutical business, Sanofi missed the deadline for the Approval Milestone and limited Lemtrada®'s use in the United States to a third-line therapy, thereby harming and materially reducing the prospects of reaching the Product Sales Milestones.

b. Sanofi failed to devote adequate resources to the promotion and commercialization of Lemtrada®, including by failing to cause Genzyme to promote and commercialize Lemtrada® in a manner normally used by other companies in the pharmaceutical business in the promotion of such a product. This failure to use efforts and employ resources normally used in the pharmaceutical business relating to the promotion and commercialization of such a product has not only led Sanofi to miss one Product Sales Milestone already, but has harmed and continues to harm and materially reduce the prospects of reaching outstanding Product Sales Milestones.

19. Sanofi's failures to use Diligent Efforts constitute a material breach of the CVR Agreement.

20. Sanofi has also materially breached the CVR Agreement by its failure to use commercially reasonable efforts to achieve the Production Milestone for Cerezyme® and Fabrazyme® on a timely basis.

21. In addition to its failures to use its contractually required efforts, Sanofi engaged in bad faith conduct designed to depress the trading price of the CVRs so as to maximize its opportunity to exercise its option to purchase the CVRs at a discount. In doing so, Sanofi has breached the implied covenant of good faith and fair dealing in the CVR Agreement.

22. Sanofi's actions and inaction have deprived the Trustee, as trustee of an express trust for the benefit of the Holders, of its right to receive payments on behalf of the Holders under the CVR Agreement and have caused damages.

23. Since the Trustee's filing of this action (the "Action"), Sanofi has continued willfully to disregard and materially breach its obligations under the CVR Agreement.

24. Sections 4.2(f) and 5.4(b) of the CVR Agreement expressly require Sanofi to comply with information requests relating to investigations initiated by the Trustee with respect to Sanofi's compliance with its obligations under the CVR Agreement. The Trustee has made requests to Sanofi for information in connection with such investigations. Sanofi has refused to comply with the Trustee's requests.

25. Section 7.6(a) of the CVR Agreement expressly requires Sanofi, upon the request of Acting Holders,[3] to submit to an independent audit of its Product Sales Statements and their underlying figures relating to Lemtrada® to assess whether Product Sales Milestone Payments should have been made. The Trustee has given notice to Sanofi of its intention to conduct such an audit. Sanofi has refused to comply with the Trustee's audit request.

26. Sanofi's wrongful conduct continues to impair the Trustee's ability to assess Sanofi's compliance with its obligations under the CVR Agreement or to assess whether Product Sales Milestone Payments should have been made by Sanofi.

[3] "Acting Holders" are "Holders of at least thirty percent (30%) of the Outstanding CVRs." CVR Agreement § 1.1.

I. Operation of the CVR Agreement

A. Sanofi's Obligations Under the CVR Milestones

27. The CVR Agreement provides that Sanofi must make certain payments to the Trustee upon the occurrence of certain events regarding Lemtrada®.

a. *Production Milestone*: Holders are entitled to receive $1.00 per CVR (the "Production Milestone Payment") in the event that production levels of Cerezyme® and Fabrazyme® hit certain production thresholds by the end of calendar year 2011.

b. *Approval Milestone*: Holders are entitled to receive $1 per CVR (the "Approval Milestone Payment") within twenty business days following the date that Sanofi or one of its Affiliates receives FDA approval of Lemtrada® for treatment of multiple sclerosis, if such date is on or before March 31, 2014 (the "Approval Milestone Deadline").

c. *Product Sales Milestone #1*: Holders are entitled to receive $2 per CVR within a defined period of time following the first instance where the sum of (i) the aggregate Lemtrada® sales for certain qualifying major markets plus (ii) the aggregate Lemtrada® sales achieved in all countries that are not qualifying major markets exceeds $400 million, during certain periods ("Product Sales Milestone #1").

d. *Product Sales Milestone #2*: Holders are entitled to receive $3 per CVR within a defined period of time after the global sales of Lemtrada® are equal to or in excess of $1.8 billion during any four consecutive quarters ("Product Sales Milestone #2"). The CVR Agreement further provides that if Product Sales Milestone #2 is achieved but the Approval Milestone is not achieved, Sanofi must

pay the Holders an additional $1 per CVR for Product Milestone #2.

e. *Product Sales Milestone #3*: Holders are entitled to receive $4 per CVR within a defined period of time after the global sales of Lemtrada® are equal to or in excess of $2.3 billion during any four consecutive quarters (exclusive of any quarters used for achievement of previous milestones) ("Product Sales Milestone #3").

f. *Product Sales Milestone #4*: Holders are entitled to receive $3 per CVR within a defined period of time after the global sales of Lemtrada® are equal to or in excess of $2.8 billion during any four consecutive quarters (exclusive of any quarters used for achievement of previous milestones) ("Product Sales Milestone #4," and, together with Product Sales Milestone #1, Product Sales Milestone #2, and Product Sales Milestone #3, the "Product Sales Milestones," and together with the Production Milestone and Approval Milestone, the "Milestones").

28. Because of Sanofi's wrongful conduct and material breach of its obligations under the CVR Agreement, Sanofi has not achieved any of the Milestones, including the Approval Milestone, the deadline for which passed on March 31, 2014, the Production Milestone, the deadline for which passed on December 31, 2011, and Product Sales Milestone #1, the deadline for which Sanofi claims to have been on June 30, 2016. The Trustee has received no payments in connection with any of the Milestones.

B. Sanofi's Obligations to Use Diligent Efforts or Commercially Reasonable Efforts Under the CVR Agreement

29. Pursuant to Section 7.10 of the CVR Agreement, Sanofi is obligated to "use Diligent Efforts to achieve the Approval Milestone and the Product Sales Milestones."

30. "Diligent Efforts," as defined in the CVR Agreement, means:

> with respect to the Product, efforts of a Person to carry out its obligations, and to cause its Affiliates and licensees to carry out their respective obligations, using such efforts and employing such resources normally used by Persons in the pharmaceutical business relating to the research, development or commercialization of a product, that is of similar market potential at a similar stage in its development or product life, taking into account issues of market exclusivity, product profile, including efficacy, safety, tolerability and convenience, the competitiveness of alternate products in the marketplace or under development, the availability of existing forms or dosages of alemtuzumab for other indications, the launch or sales of a biosimilar product, the regulatory environment and the profitability of the applicable product (including pricing and reimbursement status achieved) consistent with the Company's publicly reported financial statements (assuming the Company will not treat payments to [Bayer] as an expense for purposes of this clause, or the achievement of Milestones in such a manner, that would reduce the profitability of the Product) and other relevant factors, including technical, commercial, legal, scientific and/or medical factors. "Diligent Efforts" shall include, but shall not be limited to, the following: (a) making expenditures in relation to the Product that are consistent with expenditures normally made by Persons in the pharmaceutical business in connection with products of similar market potential at similar stages in their development or product life; (b) implementing and maintaining appropriate Product and patient support services (including, but not limited to, risk identification and minimization programs and reimbursement support services); (c) initiating and completing all post-marketing approval commitments; (d) promptly seeking pricing approvals and/or minimally restrictive payer coverage decisions in the Major Markets; (e) fulfilling obligations under any copromotion agreement or arrangement with [Bayer] should [Bayer] exercise its right to co-promote the Product; (f) setting or seeking a commercial price for the Product that is consistent with the profile of the Product, including seeking premium pricing based on the effectiveness of the Product; (g) promoting the Product for all labeled multiple sclerosis indications; and (h) otherwise fulfilling the obligations of the Company and its Affiliates under Existing Licenses, including fulfilling obligations pursuant to the LAPA in order to maintain the rights to develop and commercialize the Product granted thereunder.

31. Section 7.10 of the CVR Agreement obligates Sanofi to "use commercially reasonable efforts" to achieve the Production Milestone "on a timely basis." "Commercially reasonable efforts" is not defined in the CVR Agreement.

32. Sanofi's obligations to take certain actions to achieve the Milestones included the obligation to cause its Affiliate, Genzyme, to take certain actions so that the Milestones would be met.

C. Sanofi's Obligations to Bayer Under the CVR Agreement

33. As part of the merger with Genzyme, Sanofi also assumed Genzyme's obligations under a prior License and Asset Purchase Agreement, dated as of March 30, 2009 (the "LAPA"), with Bayer Schering Pharma AG ("Bayer"). That agreement gave Genzyme worldwide development and marketing rights to Lemtrada®, as well as the rights to another drug called "Campath," which used the same active ingredient, alemtuzumab, but was specifically developed for the treatment of chronic lymphocytic leukemia.

34. The LAPA provides that in exchange for Bayer's funding of a portion of the costs to develop Lemtrada®, Bayer is to receive, among other things, a percentage of sales of Lemtrada® and Campath® up to a maximum amount or over the course of a maximum number of years. Bayer is also entitled to certain milestone payments based on the annual sales of both Campath® (between 2011 through 2013) and Lemtrada® (after 2012).

35. As of December 31, 2014, Sanofi listed the fair value of this contingent liability to Bayer at €896 million.

D. Sanofi's Failure Purchase Option Under the CVR Agreement

36. The CVR Agreement provides Sanofi with a "Failure Purchase" option to purchase and cancel all (but not less than all) of the outstanding CVRs upon the occurrence of a "CVR Failure Event." Sanofi can exercise the Failure Purchase option any time after the Failure Purchase Eligibility Date, if both of two conditions are met:

a. the volume-weighted average price paid per CVR for all CVRs traded over the forty-five (45) trading days prior to such date is less than fifty cents ($0.50) (the "Failure Purchase Price"); and

b. "Product Sales" (as defined in the CVR Agreement) in the four (4) calendar quarters ended immediately prior to such date are less than one billion dollars

($1,000,000,000.00) in the aggregate.

37. If Sanofi properly exercises the Failure Purchase option, Sanofi must then purchase and cancel all of the outstanding CVRs at the Failure Purchase Price.

E. Sanofi's Obligation to Cooperate With the Trustee's Investigations

38. Sanofi also agreed that the Trustee may, in its sole discretion, initiate investigations into Sanofi's compliance with its obligations under the CVR Agreement.

39. Section 4.2(f) of the CVR Agreement provides, in pertinent part:

> [T]he Trustee shall not be bound to make any investigation into the facts or matters stated in any resolution, certificate, statement, instrument, opinion, report, notice, request, consent, order, approval, appraisal, bond, debenture, note, coupon, security, or other paper or document, but the Trustee in its discretion may make such further inquiry or investigation into such facts or matters as it may see fit, and if the Trustee shall determine to make such further inquiry or investigation, it shall be entitled to examine the books, records and premises of the Company, personally or by agent or attorney, as necessary for such inquiry or investigation at the sole cost of the Company . . . .

40. Section 5.4(b) of the CVR Agreement provides, in pertinent part: "The Company shall: . . . . file with the Trustee such additional information, documents and reports with respect to compliance by the Company with the conditions and covenants of this CVR Agreement as may be required from time to time by the Trustee . . . ."

F. Sanofi's Obligation to Cooperate with the Trustee's Audit Request

41. Sanofi also agreed to pay for independent audits at the request of Acting Holders audits to verify the accuracy of its Product Sales Statements relating to Lemtrada®.[4]

42. Section 7.6(a) of the CVR Agreement provides, in pertinent part:

> Upon the written request of the Acting Holders (but no more than once during any calendar year), and upon reasonable notice, the Company shall provide an independent certified public accounting firm of nationally recognized standing

[4] Under the CVR Agreement, "Product Sales Statements" consist of, in pertinent part, a quarterly written statement detailing Sanofi's aggregate sales of the Product and supporting information relating to the reported aggregate sales data.

> jointly agreed upon by the Acting Holders and the Company (failing agreement on which each shall designate an independent public accounting firm of its own selection, which firms shall in turn appoint an independent public accounting firm for such purpose) (the "Independent Accountant") with access during normal business hours to such of the records of the Company as may be reasonably necessary to verify the accuracy of the statements set forth in the Product Sales Statements and the figures underlying the calculations set forth therein for any period within the preceding three (3) years that has not previously been audited in accordance with this Section 7.6. The fees charged by such accounting firm shall be paid by the Company. The Independent Accountant shall disclose to the Acting Holders any matters directly related to their findings and shall disclose whether it has determined that any statements set forth in the Product Sales Statements are incorrect. . . .

II. Sanofi Failed to Use Diligent Efforts to Achieve the Approval Milestone

A. Sanofi and Genzyme's Inadequate Application for Lemtrada®

43. To obtain a license to introduce a biological product,[5] such as Lemtrada®, for a new particular use into interstate commerce in the United States, an entity must submit a biologics license application ("BLA") to the FDA. If the FDA has already approved a biosimilar product[6] for a different use, then the entity seeking approval must submit a supplemental biologics license application ("sBLA"). A BLA and sBLA must present specific information, data, and analyses related to the drug. *See* 21 C.F.R. § 601.20.

44. To obtain FDA approval for a license, a BLA must, among other things, present substantial evidence of a drug's efficacy by demonstrating that the clinical trials were "adequate and well-controlled." *See* 21 C.F.R. § 314.126.

45. In 2001, the FDA issued a license for the introduction into interstate commerce of alemtuzumab, marketed as Campath®, for the treatment of chronic lymphocytic

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[5] A "biological product" or "biologic" is a product made from natural resources, such as sugars, proteins, nucleic acids, or a combination of these substances, that replicates natural substances such as enzymes, antibodies, or hormones. Among other uses, biologics can be used to treat, prevent, or diagnose disease.

[6] A "biosimilar" product is a type of biological product that is highly similar to an already FDA-approved biological product (called the "reference product"), and is shown to have no clinically meaningful difference from the reference product.

leukemia.

46. After this approval, Genzyme also pursued the development of a biosimilar form of alemtuzumab for the treatment of multiple sclerosis. Over the course of the next seven years, the FDA and Genzyme were in communication concerning Genzyme's Phase II and Phase III clinical trials studying alemtuzumab for the treatment of multiple sclerosis, under the trade name Lemtrada®. During this time, the FDA communicated to Genzyme that it had significant concerns regarding the clinical trial design.

47. Genzyme was aware, through repeated communications from the FDA, that the FDA disfavored its Lemtrada® Phase III clinical trial design because the trial was not a "double-blind" trial. A "double-blind" study is a study in which neither the subjects nor the researchers know which treatment—either the drug under study or a comparator drug or placebo—a subject receives.

48. Instead of a double-blind design, Genzyme used an "open-label, rater-blind" design in the Lemtrada® clinical trials. An "open-label" study is a study in which both the subjects and the researchers know which treatment a subject receives. An "open-label, rater-blind" study is a form of an open-label study where, even though both the subject and researcher know which treatment was received, certain conditions reported by the subject are analyzed by a "rater" who is not provided with information identifying which treatment the subject received.

49. Subsequent to its acquisition by Sanofi, on or before June 12, 2012, Genzyme submitted an inadequate sBLA (as subsequently amended, the "Application") to the FDA, purportedly seeking approval of Lemtrada® for the treatment of relapsing multiple sclerosis. Sanofi caused Genzyme to submit the inadequate Application.

50. In August 2012, Sanofi and Genzyme announced that the FDA had not accepted the Application for filing and had issued a "Refuse to File" letter in response to the Application. In the "Refuse to File" letter, the FDA made specific recommendations and requests to Sanofi and Genzyme regarding the Application, and requested that Sanofi and Genzyme modify the presentation of the data in further submissions relating to the Application to enable the agency to better understand and evaluate the data within the Application. Sanofi and Genzyme's inadequate Application and the FDA's ensuing "Refuse to File" letter delayed FDA approval.

51. Three months later, in November 2012, Sanofi and Genzyme submitted a revised Application, which the FDA accepted for review in January 2013.

52. In December 2013, the FDA denied approval of Lemtrada®, taking the position that Genzyme had not submitted sufficient evidence from adequate and well-controlled studies that demonstrated that the benefits of Lemtrada® outweighed its adverse effects. Sanofi and Genzyme announced that Genzyme planned to appeal the FDA decision, and that Sanofi did not anticipate that the Approval Milestone would be met.

53. However, on April 7, 2014, only one week after the deadline for the Approval Milestone had passed, Sanofi and Genzyme announced in a Press Release that they no longer expected to pursue an appeal, but would resubmit the sBLA, with additional information to "specifically address issues previously noted by the FDA in its December 27, 2013 Complete Response Letter."

54. In April 2014, approximately two weeks after the deadline for the Approval Milestone had passed, Sanofi and Genzyme submitted an amendment to the Application. Between April 2014 and November 2014, at the FDA's request, Sanofi and

Genzyme made at least thirty-two submissions to the FDA in connection with the Application, supplying information that could have and should have been supplied in an earlier time period that would have allowed Sanofi to meet the deadline for the Approval Milestone.

55. The FDA approved Lemtrada® in November 2014, approximately seven months after the deadline for the Approval Milestone. This approval was based on the same or substantially the same clinical trial data available to Sanofi and Genzyme at the time of the previous sBLA submissions.

56. The longer a product spends pending FDA approval, the less time the manufacturer will have to sell such product to the public prior to patent expiration. The FDA's standard time period for issuing a decision on an application for a license to sell a new drug is within ten months of the submission of the application.

57. The FDA sells "Priority Review Vouchers" that grant applicants an expedited six-month review of applications for FDA approval of pharmaceutical products rather than the ten-month standard review. Sanofi recognized the value in obtaining expedited FDA approval of other of its products when, in mid-2015, Sanofi purchased a Priority Review Voucher for $245 million. Extrapolating from this $245 million purchase price, Sanofi valued the right to buy an accelerated FDA review at over $60 million per month. Although customary in the industry, Sanofi never sought to purchase a Priority Review Voucher with respect to the approval of Lemtrada®.

58. Among the ten multiple sclerosis drugs with the highest sales in 2013, FDA approval was granted an average of thirteen months after the application was filed. In contrast, because of Sanofi and Genzyme's failure to use Diligent Efforts in meeting the Approval Milestone, Lemtrada® was approved 29 months after Genzyme and Sanofi submitted

the initial application in June 2012.

B. Sanofi and Genzyme Failed to Address Known Concerns Expressed by the FDA

59. Sanofi failed to use such efforts and employ the resources normally used by companies in the pharmaceutical business to present and explain the design, execution, and results of the Lemtrada® trials in the Application to the FDA such that the Application would be approved by the deadline for the Approval Milestone, and thus materially breached its obligations under the CVR Agreement.

60. Sanofi failed to use the efforts and employ the resources normally used by a company in the pharmaceutical business by not causing Genzyme to submit an adequate Application to the FDA in November 2012, and by causing Genzyme to delay, impede, and otherwise frustrate the FDA's review of the Application, and thus materially breached its obligations under the CVR Agreement.

61. As discussed *supra*, Genzyme used an open-label, rater-blind design in the Lemtrada® clinical trials, which was disfavored by the FDA. The use of an open-label, rater-blind design meant that, in the Lemtrada® clinical trials, patients and treating physicians knew whether the patients received Lemtrada® or the comparison drug REBIF (interferon beta-1a) ("Rebif").

62. To achieve FDA approval based on an open-label, rater-blind trial, Sanofi and Genzyme would have had to adequately address and alleviate the FDA's known concerns about this type of trial. In the Application, Sanofi and Genzyme failed to do so.

63. Despite constructive feedback provided by the FDA throughout the development of Lemtrada® and during the Application process, the Application did not address the FDA's concerns about the shortcomings of the Phase III clinical trials, such as the trial

design's susceptibility to bias and its influence on clinical outcomes.

64. On November 8, 2013, the FDA released briefing materials ("Briefing Materials") in advance of the November 13, 2013 FDA Peripheral and Central Nervous System Drugs Advisory Committee (the "Advisory Committee") meeting.

65. The Briefing Materials documented that, from 2006 through 2011, the FDA advised Sanofi and Genzyme of numerous concerns it had with Genzyme's clinical trials for Lemtrada®. Such materials also described the FDA's findings that the Application failed to address the FDA's previously communicated concerns regarding the conduct of the Lemtrada® trials.

66. The concerns raised in the Briefing Materials were discussed at the November 13, 2013 Advisory Committee meeting. Significant concerns were raised regarding, among other things, Sanofi and Genzyme's failure to adequately address the effect of bias as a result of the open-label, rater-blind studies. Specifically, the FDA was concerned that there was:

- Insufficient evidence presented that Genzyme took adequate steps to control for bias in the Lemtrada® trials; and
- Inadequate evidence presented to show that the bias controls employed were adequate such that the data reliably demonstrated the efficacy of Lemtrada® regarding the two main clinical outcomes of (i) rate of disability progression (referred to as "sustained accumulation of disability" or "SAD") and (ii) relapse rate.

1. Sanofi and Genzyme Failed to Address the FDA's Concerns in the Application

67. In the Application, Sanofi and Genzyme ignored the FDA's repeated, expressed concerns about bias in the clinical trials, and the FDA's requests for specific information that would have assisted the FDA in resolving its concerns without undue delay.

68. For example, on November 13, 2013 at the Advisory Committee meeting, Dr. Billy Dunn of the FDA stated that "we [the FDA] gave [Sanofi and Genzyme] very specific

information that had to do with what types of information they could include in order to help increase a demonstration of the rigor of the trial, help us in our analysis of assessing the effects of potential bias in the trial." Transcript of the November 13, 2013 Advisory Committee Meeting, excerpts attached as Exhibit B ("Advisory Committee Tr.") at 268:12-20. This information was not included in the Application.

69. The FDA had specifically "reiterated the concerns about the lack of blinding, and requested that the applicant submit a full discussion and analysis of the impact of having the patients and treating physicians unblinded." Advisory Committee Tr. at 136:16-137:5. Sanofi and Genzyme did not "directly address[] the impact of unblinding the patients and the treating physicians" in the Application. *Id.*

70. Sanofi and Genzyme also failed to address the uneven dropout rates in the Phase III trials in the Application. In one of the Phase III studies, the dropout rate, which is the percentage of patients who dropped out of the clinical trial before receiving any treatment, was 12.6 percent for the Rebif group, as compared with 2.3 and 1.7 percent in the two Lemtrada® groups that were included in the study. Because patients were unblinded before treatment and aware of the study trial group in which they had been placed, *i.e.*, they knew whether they would be receiving the new drug under study (Lemtrada®), or the older, known drug (Rebif), the uneven dropout rate is evidence that knowledge of the treatment group may have influenced patient behavior. That is, the patients who knew they would be receiving the drug under study may have felt more positive about the results of the treatment while patients receiving Rebif, a drug already available, may have felt less positive about the treatment results. This disparity in the dropout rates for the Lemtrada® group and the Rebif group caused the FDA "great concern" that the data did not represent a randomized population. Advisory Committee

Tr. at 164:15-165:22.

71. The Application also failed to address the FDA's concerns regarding taking baseline assessments *after* patients had been informed of their treatment group. A baseline assessment is an evaluation of the status of the disability in a patient prior to treatment in a clinical trial. The patients' knowledge of their treatment assignments prior to treatment created concerns that their baseline assessment was compromised, such that this assessment was biased or potentially invalid. Advisory Committee Tr. at 164:15-165:22.

72. Further, the Application *failed* to adequately explain whether any bias from unblinding patients was adequately controlled by rater-blinding. Although the rater does not know which treatment a patient received, the raters score the disability status or neurological impairment of each patient ("EDSS" scores)[7] to measure the effect of treatment on a patient's disability. These EDSS scores were based on subjective information provided by the unblinded participants. Advisory Committee Tr. at 140:3-142:9.

73. The Application failed to address how these issues might affect the robustness of the data and the conclusions that could be drawn from the clinical outcomes. For example, Dr. Marler of the Advisory Committee expressed the following concerns:

> [W]e asked the question were adequate measures taken to minimize bias on the part of the subjects, observers, and analysts of the data. It is in the control of bias that the [Phase III Lemtrada®] trials have their most serious weaknesses. . . . First, the primary SAD [sustained accumulation of disability] and relapse events are highly dependent on subjective responses from patients and treating physicians. Second, the applicant's methods for controlling bias inherent in reports from unblinded patients and treating physicians are inadequate[.]
>
> Most of these exam items depend directly on the effort exerted by the subject to perform a test, describe a feeling, or recall a symptom. This is what I mean when I say subjective. [sic] Conclusion. Although there are hundreds of items

[7] "EDSS" is the Kurtzke Expanded Disability Status Scale, a widely used, standard assessment that measures the disability status or neurological impairment of patients with multiple sclerosis.

> recorded, the EDSS is very subjective, relying heavily on the patient's subjective observations.
>
> The bias that the trial protocols permit in the underlying EDSS scores by unblinding the patients, and to some extent the treating physician, is carried forward into the determination of disability events. Hence, blinding EDSS raters does not control bias introduced by patients and treating physicians in the determination of the SAD outcome because the EDSS scores are themselves biased.

Advisory Committee Tr. at 140:3-142:9.

74. Additionally, the Application failed to adequately address the effect of bias based on the subjective nature of the patient examination and the patient's knowledge of the treatment being received in the findings on the efficacy of Lemtrada® on relapse rates. Dr. Marler expressed the following concern:

> The main point here is that all the data that the Relapse Adjudication Panel looks at originated from an unblinded source, the patient primarily and the treating physician secondarily. . . . The Relapse Adjudication Panel had no untainted source of information and, hence, could not distinguish the effects of alemtuzumab or interferon from those of bias, placebo effects, and baseline differences in the study population. . . . So the conclusion about this second characteristic is that the [Phase III Lemtrada®] trials did not adequately control bias on the part of the subjects and the treating physicians.

Advisory Committee Tr. at 146:6-147:8.

75. The Briefing Materials included the following statement summarizing Sanofi and Genzyme's failure to present an adequate Application:

> In general, the application did not convey objectivity and did not explore alternative explanations for the results that were reported. The submission did not explain unusual features of the trial such as the determination of baseline EDSS scores after randomization in many subjects. The discussion of the blinding was incomplete and did not adequately address FDA concerns about the extent of bias introduced by unblinded subjects and treating physicians or estimate the possible effects of unblinding patients and treating physicians on the interpretation of the results. Briefing Materials at 20 (excerpts attached hereto as Exhibit C).

2. Sanofi and Genzyme's Expressed Rationales to the FDA for Not Conducting Double-Blind Clinical Trials Were Inadequate

76. Sanofi and Genzyme also did not present to the FDA adequate rationales as to why they did not conduct a double-blind study. During the November 13, 2013 meeting, Sanofi and Genzyme representatives stated that among the rationales for not pursuing a double-blind study were that, even if a double-blind study had been pursued, (i) the use of Rebif as a comparison drug and (ii) the known side effects of Lemtrada® (namely, a significant rash on most patients) would have effectively unblinded the study participants. *See* Advisory Committee Tr. at 121:15-124:18.

77. Sanofi and Genzyme's stated rationales to the FDA for not conducting a double-blind study were inadequate.

78. Sanofi and Genzyme's first rationale—the use of the comparison drug, Rebif—was inadequate, in part, because other pharmaceutical companies have conducted double-blind clinical trials for drugs similar to Lemtrada®, using the same comparison drug.

79. For example, F. Hoffman La Roche Ltd. ("Roche") conducted two double-blind, double-dummy[8] Phase III clinical trials (hereinafter, the "Roche Double-Blind MS Studies") to evaluate the efficacy and safety of a drug called "ocrelizumab" which, like Lemtrada®, is a treatment for people with relapsing multiple sclerosis.

80. In the Roche Double-Blind MS Studies, ocrelizumab was compared against administration of Rebif, the same drug that Genzyme used as a comparison in its

[8] A "double-blind, double-dummy" study is a type of double-blind study in which all subjects are given both a placebo and an active drug in alternating study periods. Neither the subjects nor the researchers know which treatments the subject receives. This type of study is used when studying two treatments that cannot be made identical, such as when comparing a drug administered by intravenous infusion (such as Lemtrada®) to a drug administered by injection (such as Rebif). In that example, the patient groups in a double-dummy study may receive the following: Group 1 (active intravenous infusion, placebo injection), Group 2 (placebo intravenous infusion, active injection), Group 3 (placebo intravenous infusion, placebo injection).

rater-blinded studies. Unlike Lemtrada® and ocrelizumab, which are both administered by intravenous infusion, Rebif is administered by subcutaneous injection three times per week.

81. The Roche Double-Blind MS Studies had other similarities with Genzyme's Phase III clinical trials for Lemtrada®. Both Lemtrada® and ocrelizumab are biological drugs for the treatment of patients with multiple sclerosis, and both trials primarily compared the effects of either the drug under study or Rebif on the two clinical outcomes of (i) rate of disability progression and (ii) relapse rate over a two-year period in patients that were administered either the drug under study or Rebif.

82. Thus, by virtue of the fact that Roche was able to conduct a double-blind, double-dummy study with Rebif, the same comparison drug, Sanofi and Genzyme's expressed rationale that use of Rebif would have effectively unblinded the study participants was inadequate to justify conducting an open-label study rather than a double-blind study.

83. Sanofi and Genzyme's second expressed rationale for not using a double-blind trial—that patients and researchers would have become unblinded based on Lemtrada®'s infusion-related side effects—was similarly inadequate because patients that received the comparison drug, Rebif, also experienced infusion-related side effects associated with the infusion of the steroid methylprednisolone, a part of treatment with Rebif. *See* Advisory Committee Tr. at 327:21-328:7 (FDA noting that those patients also had "a fairly high rate of [side-effect] events at the time of infusion even though they knew that they were not alemtuzumab"). As the FDA itself noted, the fact that patients receiving Rebif also experienced infusion-related side effects "is actually the best argument ***for*** a double-dummy study." *Id.* (emphasis added).

84. Thus, Sanofi and Genzyme's second stated rationale for not using a

double-blind study, that of the known side effects of Lemtrada®, was also inadequate to justify their use of a rater-blind study.

C. Sanofi's Failure to Use Diligent Efforts Resulted in the FDA's Denial of the Application and the Failure to Meet the Approval Milestone

85. Sanofi and Genzyme's failure to adequately present to the FDA the evidence obtained from the clinical trials, coupled with insufficient rationales for their trial design, caused the FDA to deny approval of Lemtrada® prior to the Approval Milestone Deadline.

86. In denying the Application, the FDA issued a Complete Response Letter on December 27, 2013, explaining that it had determined that Sanofi and Genzyme did not provide evidence from adequate and well-controlled studies to support the effectiveness of Lemtrada® for treating multiple sclerosis.

87. Although the deadline for the Approval Milestone was March 31, 2014, Sanofi and Genzyme delayed submitting pertinent information to the FDA until after that deadline had passed and for almost four months from the denial of the Application. As soon as the Approval Milestone deadline passed, Sanofi ramped up the activity. Between April and November 2014, Sanofi and Genzyme made at least thirty-two additional submissions relating to the Application. Sanofi and Genzyme made one or more submissions to the FDA relating to the Application on each of the following dates: April 15, 2014, May 15, 2014, May 20, 2014, June 13, 2014, July 1, 2014, July 2, 2014, July 10, 2014, July 15, 2014, July 18, 2014, July 21, 2014, July 22, 2014, July 23, 2014, July 29, 2014, July 30, 2014, August 4, 2014, August 6, 2014, August 7, 2014, August 8, 2014, August 27, 2014, September 5, 2014, September 8, 2014, September 12, 2014, October 15, 2014, October 21, 2014, October 27, 2014, November 7, 2014, November 12, 2014, November 13, 2014, and November 14, 2014.

88. These thirty-two submissions were based on the data from the ***same clinical trials*** that were discussed in previous submissions related to the Application. The FDA approved the Application on November 14, 2014.

89. Sanofi's delay in achieving FDA approval adversely affected sales of Lemtrada® all over the globe. As Sanofi's CEO, Christopher Viehbacher, stated in an investor call on October 28, 2014, "if the FDA does not approve a product straight away, even if you get it approved elsewhere, there is still a 'waiting to see what the FDA does'." Sanofi's failure to use Diligent Efforts to achieve the Approval Sales Milestone has caused Sanofi to miss the Product Sales Milestone #1, and continues to adversely affect Sanofi's ability to meet each of the other Product Sales Milestones.

D. Sanofi's Failure to Use Diligent Efforts Resulted in the FDA Limiting Lemtrada® to a Third-Line Therapy

90. In the Application, Sanofi and Genzyme failed to address the FDA's safety concerns associated with the use of Lemtrada®. The safety data from the clinical trials for Lemtrada® revealed that use of Lemtrada® is associated with increased risk for malignancies such as thyroid cancer and melanoma, infusion reactions, infections, and autoimmune diseases such as thyroid disorders, immune thrombocytopenia and hemophilia. For example, more than eighteen (18%) percent of patients receiving Lemtrada® in the clinical trials reported a thyroid adverse event over a three-year period compared with five percent (5%) of patients receiving Rebif in the clinical trials over the same time period. Genzyme was aware of these safety issues as early September 2005 when the FDA placed a clinical hold on the Lemtrada® Phase II studies after the occurrence of three cases of severe immune thrombocytopenia in patients receiving Lemtrada® while none of the patients receiving Rebif in the clinical trials had confirmed immune thrombocytopenia. *See* Briefing Materials at 15-16.

91. Given the known safety profile for Lemtrada®, in the exercise of Diligent Efforts Sanofi should have conducted and sponsored additional trials to determine how to manage and mitigate the side effects of Lemtrada®, but it undertook no such effort. At the November 13, 2013 Advisory Committee meeting, Dr. Nyedra Booker of the FDA stated that "there is no specific strategies that have been identified [by Sanofi and Genzyme] that will prevent or lessen the frequency of the serious adverse events" based on the use of Lemtrada®. Advisory Committee Tr. at 199:21¬200:1.

92. Because of Sanofi and Genzyme's failure to use Diligent Efforts and to explain the management or mitigation of these side effects in the Application, the FDA approval required the marketing of Lemtrada® as a "third-line" therapy, generally reserved for patients who have had an inadequate response to two or more drugs for the treatment of multiple sclerosis.

93. Because of the known safety profile for Lemtrada®, the FDA also required that Sanofi and Genzyme put a Risk Evaluation and Mitigation Strategy ("REMS") program in place prior to approval of the Application. A REMS program is intended to ensure that the benefits of a drug or biologic outweigh its risks.[9] Sanofi and Genzyme should have developed a REMS program for Lemtrada® that ensured adequate screening and monitoring for managing side effects in patients and more detailed follow-up and reporting of adverse events in treated patients. If Sanofi and Genzyme had used the efforts and employed the resources normally used by pharmaceutical companies, they would have developed a REMS program that would have resulted in Lemtrada®'s approval as a first-line or second-line therapy.

[9] A REMS program includes specific safety procedures required of healthcare professionals and distributors prior to prescribing, shipping, or dispensing a drug. These procedures may include specialized drug labeling, patient education through a medication guide or patient package insert, the requirement that healthcare professionals be certified to administer or dispense a drug, and additional monitoring or testing of a patient prior to or during administration of a drug.

94. Sanofi and Genzyme's failure to conduct additional trials to manage and mitigate the known side effects of Lemtrada® and to develop an appropriate REMS program led to the FDA limiting Lemtrada®'s use to a third-line therapy, thereby harming the prospects of reaching the Product Sales Milestones.

III. Sanofi Did Not Use Diligent Efforts to Commercialize and Promote Lemtrada

95. Sanofi also failed to use Diligent Efforts, including failing to cause Genzyme to take certain actions, to achieve the Product Sales Milestones.

96. Sanofi did not use the efforts or employ the resources normally used by companies in the pharmaceutical business to commercialize and promote Lemtrada®, which resulted in depressed sales because Lemtrada® was introduced into a healthcare professional and consumer market that was unfamiliar with Lemtrada®.

97. For example, Sanofi did not use the efforts or employ the resources or make the expenditures normally used by companies in the pharmaceutical business to provide patients with support and information about Lemtrada® or to inform doctors about Lemtrada®. Among other things, Sanofi:

- Failed to timely commence a marketing campaign commensurate with the marketing campaigns of other companies in the pharmaceutical business after regulatory approval of Lemtrada®. Indeed, in December 2014, a healthcare marketing business publication called Medical Marketing & Media reported that Sanofi was keeping Lemtrada® consumer marketing materials from rolling out until at least six months after approval.

- Failed to put the Lemtrada® sales force fully into place until February 2015, at least two months after the first commercial sale in the United States, and 15 months after the first worldwide commercial sale in Germany. Had Sanofi acted earlier, sales would have been substantially increased. In the first full quarter after the hiring of the sales force, sales for Lemtrada® nearly doubled in the United States. In the first quarter where consumer marketing materials were made available, sales increased in the United States by another 30%.

- Failed to provide sufficient information to neurologists and provide sufficient

physician and other relevant training for Lemtrada®.

- Failed to locate and develop an adequate amount of infusion centers, especially in highly populated areas, to ensure patient access to Lemtrada® treatment.
- Failed to meaningfully operate patient resources campaigns for Lemtrada®.

98. These failures assured that sales would be depressed during the measuring period for the Product Sales Milestone #1, especially in the United States market, where, as Bill Sibold, senior vice president of Genzyme, acknowledged, "[a]bout 60 percent of the global market for multiple sclerosis is[.]" Had Sanofi taken actions normally used by companies in the pharmaceutical business to commercialize Lemtrada®, including but not limited to, promoting Lemtrada®, hiring and building out a sales force, providing sufficient information to physicians along with other relevant training, and making appropriate expenditures relating to the foregoing, sales during this period would have been significantly greater such that Sanofi would have achieved Product Sales Milestone #1 as early as the second quarter of 2015, but no later than the third quarter of 2015.

99. Instead, Product Sales Milestone #1 has not been met. On October 29, 2015, Sanofi announced that "[b]ased upon actual sales trends to date, Sanofi does not expect that the Product Sales Milestone #1 will be met." On June 30, 2016, Sanofi announced "[b]ased upon actual sales of Lemtrada® in Qualifying Major Markets and in other markets during the respective applicable periods since the Product Launch, Product Sales Milestone #1 has not been met."

A. Sanofi's Efforts With Respect to the Commercialization and Promotion of a Competitor Drug, Aubagio®

100. Sanofi's promotion and commercialization of its competitor drug, Aubagio®, for the treatment of multiple sclerosis, demonstrates that Sanofi failed to use efforts and employ the resources normally used by pharmaceutical companies to commercialize and

promote Lemtrada®.

101. Upon information and belief, Sanofi is not obligated to make any contingent payments to any entity as a result of the regulatory approval or sales of Aubagio® similar to those contingent payments associated with sales of Lemtrada® (*i.e.*, the Approval Milestone Payment, the Product Sales Milestone payments, and the payments to Bayer under the LAPA).

102. In contrast to the inadequate efforts and resources Sanofi devoted to promoting and commercializing Lemtrada®, Sanofi devoted significant efforts and resources into developing, promoting, and commercializing its competitor drug Aubagio®.

103. In August 2011, Sanofi submitted a drug application to the FDA for approval to sell Aubagio® for the treatment of relapsing multiple sclerosis, the same condition for which Lemtrada® is indicated. Just over a year later, in September 2012, the FDA approved Aubagio®.

104. Sanofi devoted substantially more efforts and resources to the hiring and training of the Aubagio® sales team than to the Lemtrada® sales team. In an interview with a pharmaceutical marketing news outlet, Carole Huntsman, Genzyme VP and Business Unit Head, acknowledged that "[i]n contrast with the Lemtrada® staff, the Aubagio® team came together 'really quickly' before the product's FDA approval." David Meeker, President and CEO of Genzyme, also stated on an investor earnings call on July 7, 2015, that "we put the [Lemtrada®] sales force fully in place only at the beginning of February", which was at least two months after FDA approval.

105. Sanofi and Genzyme conduct over 50% more consumer marketing events for Aubagio® than they do for Lemtrada®.

106. Sanofi and Genzyme provide more opportunities for patients who are taking Aubagio® to share their experiences with other members of the multiple sclerosis community than Sanofi and Genzyme do for patients who have taken Lemtrada®. Sanofi and Genzyme provide a website (https://www.aubagio.com/tell-your-story) in which patients who have taken Aubagio® can offer to share their experiences with other members of the multiple sclerosis community and participate in Sanofi and Genzyme's "Ambassador" program. Sanofi and Genzyme do not provide a website inviting patients who have taken Lemtrada® to share their experiences with other members of the multiple sclerosis community or participate in Sanofi and Genzyme's "Ambassador" program.

107. On a Sanofi- and Genzyme-sponsored website, Sanofi and Genzyme do not promote Lemtrada®. Genzyme's website for Aubagio® identifies nine different oral and injectable treatment options for patients with relapsing multiple sclerosis offered by different companies but does not identify Lemtrada® as an available treatment option for patients with relapsing multiple sclerosis (https://www.aubagio.com/ms-medications).

108. Additionally, Sanofi and Genzyme provide more publicly available information about the necessary steps patients must take before beginning treatment with Aubagio® than they do for patients who are preparing to begin treatment with Lemtrada® (https://www.aubagio.com/starting-aubagio). Sanofi and Genzyme do not provide a website informing patients about the necessary steps patients must take before beginning treatment of Lemtrada®. This lack of information about Lemtrada® makes it much less likely that doctors and patients will consider Lemtrada® as a treatment option and eventually prescribe or receive the treatment.

109. In early 2013, approximately five months after approval of Aubagio®,

Sanofi touted the success of the Aubagio® launch to its investors, reporting that over 80% of multiple sclerosis specialists in the U.S. had prescribed Aubagio® and that Aubagio® had a comparable growth trajectory in its initial weeks to the growth trajectory in the initial weeks of a previous blockbuster multiple sclerosis drug, Gilenya. By contrast, on a February 5, 2015 earnings call for Sanofi, nearly three months after approval of Lemtrada®, Genzyme's CEO could only report that the Lemtrada® team "just had our launch meeting here in the U.S." and only in the start of February was its sales force "fully deployed."

110. The following table compares the timeline of FDA approval and net sales for Aubagio® and Lemtrada®.

	AUBAGIO®	**LEMTRADA®**
FDA Application	August 2011	June 2012
FDA Approval	September 2012 (11 months)	November 2014 (29 months)
End-of-Year Net Sales	€7 million (2012)	€2 million (2013)
Year 1 Net Sales	€166 million (2013)	€34 million (2014)
Year 2 Net Sales	€443 million (2014)	€94 million (first-half 2015)

111. Had Sanofi and Genzyme used Diligent Efforts to commercialize and promote Lemtrada®, including but not limited to making appropriate expenditures to commercialize and promote Lemtrada®, the Product Sales for Lemtrada® would have been significantly higher, and Product Sales Milestone #1 would have been met as early as the second quarter of 2015, and no later than the third quarter of 2015.

112. Sanofi's failure to meet Product Sales Milestone #1 by at least the third quarter of 2015 continues to adversely affect Sanofi's ability to meet each of the other Product Sales Milestones.

B. Sanofi Failed to Use Efforts and Employ Resources Normally Used by Pharmaceutical Companies to Launch Lemtrada® in International Markets in a Timely Fashion

113. In February 2014, Genzyme President and CEO David Meeker announced that Sanofi "plans this year [2014] to launch Lemtrada® in more than 30 countries, and hopefully additional markets where the treatment is still under review[.]" By the end of 2014, however, Sanofi had made sales of Lemtrada® in only three of the six "Major Markets" identified in the CVR Agreement (the United States, the United Kingdom, France, Germany, Italy, and Spain) and fell dramatically short of its launch target.

114. Sanofi's home market, France, is one of six Major Markets, but more than two years after Lemtrada® was approved in the European Union and more than two years after the first sale of Lemtrada® in Germany, Sanofi has not sold a single dose of Lemtrada® in France. In order for Product Sales in France to qualify in the calculation of Product Sales Milestone #1 (as a "Qualifying Major Market"), the first commercial sale in France must be made on or before December 31, 2015 (according to Sanofi's position as to the timing of Product Launch). Because of Sanofi's failure to use Diligent Efforts to promote and commercialize Lemtrada®, France has not become a Qualifying Major Market to date, which has adversely affected Sanofi's ability to meet the Product Sales Milestones.

115. In contrast to the Lemtrada® sales efforts, Sanofi's CEO Olivier Brandicourt boasted in an October 29, 2015 third-quarter earnings call that "Aubagio is now Genzyme's largest product by sales, driven by strong growth in the U.S., but also France[.]"

C. Sanofi Failed to Use Efforts and Employ Resources Normally Used by Pharmaceutical Companies to Develop and Commercialize Lemtrada® in Light of the Known 2017 Patent Expiration

116. Diligent Efforts require Sanofi to use such efforts and employ such resources normally used by companies in the pharmaceutical business in the development and

commercialization of Lemtrada®, taking into account the launch or sales of a biosimilar product (which would include "generic" drugs).

117. U.S. Patent No. 6,120,766 (the "Lemtrada® Patent") was issued on September 19, 2000. The Lemtrada® Patent includes at least one claim that covers the use of Lemtrada® as prescribed for multiple sclerosis.

118. No patent term extension is available for the Lemtrada® Patent under applicable law. All other U.S. patents covering Lemtrada® or its use will expire prior to September 19, 2017.

119. After September 19, 2017, Sanofi will not be able to prevent another company that obtains approval from the FDA and meets other statutory requirements from being able to sell a drug that is biosimilar to Lemtrada®.

120. After expiration of the Lemtrada® Patent, Sanofi will likely be forced to sell Lemtrada® at a lower price and will generate less revenue from Lemtrada® sales than they otherwise could have because generic manufacturers will be able to market and sell a drug that is biosimilar to Lemtrada® after September 19, 2017.

121. Faced with the known expiration of the Lemtrada® Patent, a company using normal efforts and resources in the pharmaceutical business would have sought to obtain approval of Lemtrada® in a manner that would maximize the period of time that Lemtrada® could be sold under patent protection at a higher price. Sanofi did not undertake Diligent Efforts with respect to, and did not maximize the commercialization potential of, Lemtrada®.

122. Sanofi's failure to devote the required efforts in light of the known expiration of the Lemtrada® Patent adversely affected and continues to adversely affect Sanofi's ability to meet each of the Product Sales Milestones.

IV. Sanofi Failed to Use Diligent Efforts in Achieving the Milestones Because it Took Into Account CVR Agreement Milestone Payments and Payments to Bayer in Evaluating the Profitability of Lemtrada

123. Sanofi failed to use Diligent Efforts because it took into account the Milestone Payments to the Trustee and the Bayer royalty payments when evaluating the profitability of Lemtrada®.

124. Under the CVR Agreement, "Diligent Efforts" is defined as "such efforts and employing such resources normally used by Persons in the pharmaceutical business relating to the research, development or commercialization of a product" similar to Lemtrada®, and taking into account certain issues including, but not limited to, Lemtrada®'s profitability. *See* paragraph 30, *supra*. Sanofi is not permitted to "treat royalty payments to [Bayer] as an expense. . . , or the achievement of Milestones in such a manner, that would reduce the profitability of the Product[.]" Sanofi materially breached its obligations under the CVR Agreement because it treated the royalty payments to Bayer as an expense and took into account the Milestone Payments and obligations to Bayer in a manner that reduced profitability for Lemtrada®.

125. In material breach of the express provision of the CVR Agreement, Sanofi took into account the negative impact that these Milestone Payment obligations would have on its profitability in determining how to promote and commercialize Lemtrada®. For example, had Sanofi met Product Sales Milestone #1 (*i.e.*, had Sanofi reached the required minimum of $400 million in sales during the contractually defined sales period), Sanofi would have been required to make a $472 million payment to the Trustee, as trustee of an express trust for the benefit of the Holders, and another substantial payment to Bayer.

V. Sanofi Breached the Implied Covenant of Good Faith and Fair Dealing

126. After issuing the CVRs to entice the Genzyme shareholders to agree to the acquisition by Sanofi, Sanofi engaged in conduct designed to keep Lemtrada® sales volume low,

delay the achievement of the Milestones, and depress the trading price of the CVRs.

127. Sanofi's delay in obtaining U.S. regulatory approval delayed sales of Lemtrada®. In addition, Sanofi has kept the sales volume of Lemtrada® low by failing to adequately promote and commercialize Lemtrada®.

128. Sanofi has an incentive to engage in the foregoing conduct because of the Failure Purchase option. As explained *supra*, ¶¶ 36-37, the Failure Purchase option allows Sanofi to purchase and cancel all outstanding CVRs if the sales of Lemtrada® and trading price of the shares (traded under the symbol "GCVRZ") remain below certain thresholds. By keeping sales volume low and failing to meet the Milestones, the GCVRZ trading price has been and continues to be depressed, which, in turn, maximizes Sanofi's opportunity to exercise the Failure Purchase option.

129. Sanofi is further incentivized to depress the value and the trading price of the CVRs as Sanofi records an income when the value of the CVRs drops. Since the acquisition of Genzyme, Sanofi has recorded hundreds of millions of euros in income as a direct result of the drop in the market value of the CVRs. In the third quarter of 2015 alone, while the Holders suffered a 73% drop in the value of the CVRs, Sanofi reported an income of €109 million resulting from "a decrease in the fair value of contingent considerations related to the CVRs[.]"

130. The CVRs were an assurance to Genzyme's former shareholders that they would be adequately compensated in the Sanofi merger. By breaching its obligations under the CVR Agreement and acting in bad faith to keep Lemtrada® sales volume low, delay the achievement of the Milestones, and depress the trading price of the CVRs, Sanofi has by its wrongful conduct created the possibility of purchasing and canceling all of the outstanding CVRs, thereby attempting to stop the accrual of revenue-sharing costs associated with the

Milestones, and attempting to extinguish a large contingent liability on its balance sheet. Sanofi's breach of its obligations under the CVR Agreement and its wrongful actions have stripped, and will strip, the Trustee, on behalf of the Holders, of the benefit of its bargain.

VI. Sanofi Failed to Use the Required "Commercially Reasonable Efforts" to Achieve the Production Milestone.

131. The Production Milestone relates to the production of approved drugs known as Cerezyme® and Fabrazyme®.

132. After the merger with Genzyme closed, Sanofi failed to use commercially reasonable efforts and materially breached its obligations under the CVR Agreement to achieve the Production Milestone on a timely basis, including the following:

- Sanofi delayed any implementation of any efforts to achieve the Production Milestone until months after the merger was completed and its obligations to take efforts had begun;
- Sanofi oversaw a crippling departure of employee talent and institutional knowledge;
- Sanofi delayed implementing helpful manufacturing process improvements that were already in its possession and control;
- Sanofi failed to provide necessary resources to facilitate production;
- Sanofi failed to make certain facilities operational that would have boosted production; and
- Sanofi gave up completely on achieving the Production Milestone five months before the milestone's deadline.

133. Conveniently, Sanofi reached the full level of Cerezyme® and Fabrazyme® production needed to meet the Production Milestone only three months after the deadline for the Production Milestone had passed.

134. As a result of its wrongful conduct, the Production Milestone was missed and Sanofi avoided paying almost $300 million (not including interest) to Holders (former Genzyme shareholders) that it would have paid had it not abdicated its contractually obligated

efforts to reach this milestone.

135. As a result of its wrongful conduct, Sanofi did not pay anything to the Holders on the Production Milestone at the end of 2011, but, by the end of 2012, Sanofi had made over €900,000,000 on sales of Cerezyme® and Fabrazyme®.

136. Indeed, also by the end 2012, less than a year after the deadline for the Production Milestone had passed, Sanofi was able to report that Cerezyme® and Fabrazyme® sales had increased sufficiently to allow Genzyme to deliver a 22.5% sales growth in a quarter in which Sanofi saw net income fall 7.4%.

A. Genzyme discovered and developed Cerezyme® and Fabrazyme® as replacement enzyme therapies for rare genetic diseases.

137. Genzyme pioneered two therapies (Cerezyme® and Fabrazyme®) for the treatment of orphan, or rare, genetic diseases.[10] These diseases are caused by genetic defects that cause a deficiency of certain necessary enzymes. Replacement therapies attempt to replace the body's missing enzyme with one that is externally manufactured.

138. In the case of the production process here, a modified version of the genetic code for the replacement enzyme is inserted into the DNA of a host cell. Those host cells are then grown in large fermenters under carefully controlled conditions commonly referred to as current Good Manufacturing Practices ("cGMP"). As described in more detail below, this process is complex and regulated by the Food and Drug Administration (the "FDA").

139. Gaucher Disease is a rare genetic disorder that results in the buildup of certain fatty substances in certain organs, particularly the spleen and liver. Due to this accumulation, the organs become much larger than normal, and their function can be impaired.

[10] Genzyme was an innovator in the treatment of rare or orphan diseases, as dramatized in the 2010 motion picture *Extraordinary Measures*.

The fatty substances associated with Gaucher Disease also can build up in bone tissue. This weakens the bone and increases the risk of fractures. If the bone marrow is affected, it can interfere with the blood's ability to clot.

140. Gaucher Disease is the result of an inherited deficiency in an enzyme that is responsible for breaking down the fatty substance at issue. The standard therapy for the disease is enzyme replacement.

141. Using innovative techniques, scientists at Genzyme discovered a way to clone the human gene for the needed enzyme into a host cell and produce a recombinant version of that enzyme. That enzyme, known as imiglucerase, was developed by Genzyme and, in 1994, was approved for the treatment of Type I Gaucher Disease. It is sold under the tradename Cerezyme® and is the drug Cerezyme® referred to in the CVR Agreement.

142. Fabry Disease is also a rare genetic disorder that results in the buildup of certain fatty substances in blood vessel walls throughout the body. The primary defect which allows this to occur is the inherited deficiency of another enzyme, which is normally responsible for the breakdown of this fatty substance.

143. In patients with Fabry Disease, the accumulation of fatty substances causes blood vessels to become narrowed. This narrowing often occurs in blood vessels throughout the body, but particularly affects vessels in the skin, kidneys, heart, brain, and nervous system. This can cause severe pain.

144. While physicians can treat some of the side-effects of Fabry Disease, many patients have found relief with another enzyme replacement therapy pioneered by Genzyme.

145. This replacement therapy was discovered by scientists at Genzyme as a way to clone the human gene for the deficient enzyme into a host cell. That product is known as Fabrazyme® (agalsidase beta) and is a recombinant enzyme with the same amino acid sequence as the native enzyme. It was approved by the FDA in April 2003 and is also produced under cGMP conditions as a replacement therapy. It is sold under the tradename Fabrazyme® and is the drug Fabrazyme® referred to in the CVR Agreement.

B. Genzyme manufactured Fabrazyme® and Cerezyme® using sophisticated production methods to grow the necessary replacement enzymes.

146. By June 2009, Fabrazyme® and Cerezyme® were two of the most successful biotechnology products ever. As two of Genzyme's flagship products, Fabrazyme® and Cerezyme® brought in over a billion dollars per year.

147. In 2009, Fabrazyme® and Cerezyme® were being manufactured at a protein-manufacturing plant in Allston Landing, Massachusetts (the "Allston Landing Facility").

148. The Allston Landing Facility was a classic biotechnology production facility and used large stainless steel containers, known as bioreactors, to produce the two products at issue in this complaint using standard industry bio-fermentation techniques.

149. The process of recombinant protein manufacturing is complex and highly regulated by the FDA. Each product on approval has a specific section of the regulatory filings (known as the Biologics Licensing Application or "BLA") dedicated to describing or characterizing the product. Known as the Chemistry, Manufacturing, and Controls (or "CMC") section, for a BLA it describes not only the product that will be put into humans, but how the product is manufactured.

150. Many sophisticated techniques and tools can be brought to bear to improve the efficiency of the manufacturing process. The general goal is to find a stable line of

cells, with the best profile from a safety perspective, that will produce the maximum amount of the enzyme being expressed. If the cell line is not stable, yields may be variable or the cell line may need to be replaced more often, reducing the effective yield of the cell line.

151. As of 2009, the Allston Landing Facility had six 2000 liter bioreactor tanks for holding the cells as they grow and produce the enzyme at issue. According to Genzyme's 2009 Annual Report, two of the bioreactor tanks were used for production of Fabrazyme® and the other four were used for production of Cerezyme®.

152. After the enzymes are grown in the bioreactor tanks, the enzymes to be used as treatment must be separated out from the cells and liquid required for their growth. This utilizes a process called chromatography, followed by purification of the enzyme, and finally "fill and finish" of the product. These post-bioreactor processes are known as "downstream" processes.

C. Genzyme has contamination problems at Allston Landing Production Facility and eventually enters into a Consent Decree with FDA.

153. Before 2012, the entirety of the manufacture and fill and finish for Fabrazyme® and Cerezyme® was undertaken at the Allston Landing Facility.

154. In June 2009, Genzyme announced that it was halting production of Fabrazyme® and Cerezyme® due to the presence of contamination. Immediately upon discovery of the contamination, Genzyme initiated an aggressive decontamination procedure.

155. The FDA informed Genzyme that it would inspect the Allston Landing Facility and on August 14, 2009, Genzyme senior management wrote to the FDA to address the agency's concerns. The letter stated that Genzyme planned to make "fundamental systemic and cultural change." Part of that effort was a comprehensive remediation plan, overseen by a third

party contractor identified as The Quantic Group, which was submitted to the FDA in October of 2009.

156. Shortly after the production halt in 2009, Genzyme was still confident that it would bring supplies of Fabrazyme® and Cerezyme® back to market demand levels. In part, this was because Genzyme was in the late stages of construction on a new plant in Framingham, Massachusetts (the "Framingham Facility"), for the production of Fabrazyme® and Cerezyme®. Initial construction for the Framingham Facility was announced in 2007. It was planned to be, and is now a part of, a larger $300 million manufacturing complex.

157. Ultimately, the FDA and Genzyme entered into a consent decree (the "Consent Decree") requiring, among other things, Genzyme to pay a civil penalty of $175 million, to transfer fill and finish operations out of the Allston Landing Facility, and to implement a comprehensive remediation plan under the oversight of an independent expert approved by the FDA.

D. Genzyme makes remediation plan, brings in new management, and begins to ramp up Fabrazyme® and Cerezyme® production.

158. In order to assist in the remediation and to ensure that its manufacturing would be up to the requisite legal and industry requirements, in February 2010 Genzyme appointed Scott Canute as President of Global Manufacturing. Mr. Canute had many years of experience in the pharmaceutical industry, including as President, Global Manufacturing Operations for Eli Lilly and Company. In that capacity, Mr. Canute directed all manufacturing and supply chain activities for Eli Lilly's global operations. He also oversaw twenty-four sites and eighty-four contract manufacturers, as well as over eleven thousand manufacturing employees.

159. As the then CEO of Genzyme stated:

> Scott Canute is among the very top people in the pharmaceutical manufacturing field. He is widely respected for transforming manufacturing operations at Lilly and establishing its programs as a standard for the industry. His experience will accelerate efforts to strengthen our manufacturing sites, and consistently meet standards. I look forward to helping the company achieve the manufacturing capabilities that are necessary to fully serve the patients that depend on our products - both now and in the future.

160. In January 2010, Genzyme also hired Ron Branning as Senior Vice President of Global Product Quality. Genzyme noted at the time: "[Mr. Branning] has managed quality and compliance programs for global companies with diverse products, and has successfully led organizations through significant manufacturing events."

161. Mr. Canute not only brought a wealth of experience, but also recruited a team of individuals from different companies, each one of whom came with a unique perspective and skill set.

162. From the beginning of his tenure, Mr. Canute expressed realistic confidence in his ability to get Fabrazyme® and Cerezyme® manufacturing and fill and finish back on track. In March 2010, as part of a presentation showing the substantial efforts Genzyme had put into remediation, he reviewed his plans to bring Genzyme not only into compliance with applicable regulations, but to expand and insure additional capacity for Genzyme's flagship products.

163. Citing prior experience with similar problems, Mr. Canute identified specific tasks at Genzyme already underway and additional steps to be completed in the near future to ensure production would be back at least to historical levels. Included in this were completion of the expansion of existing infrastructure, improvement to the working cell banks used to manufacture Fabrazyme®, and an exit to fill and finish at the Allston Landing Facility.

164. Implicitly noting the importance of the cohesion of the team he was building, Mr. Canute stated that: "we know what needs to be done […] and most importantly, we (Ron and I) have done it before." However, he did give a prescient warning: "The most important thing going forward is to ensure a stable environment to execute our plan."

165. Even Sanofi later touted Mr. Canute and his team: "Genzyme has brought in some very strong people. Both Scott Canute and Ron Branning who've come in in the last year have done wonders in terms of really getting the manufacturing turned around."

166. Genzyme's plans for resuming the manufacture of Fabrazyme® and Cerezyme® were relatively straightforward.

- First, resume production at the Allston Landing Facility with processes newly approved by the FDA.
- Second, move fill and finish for the United States to a third-party provider in Kansas and, for Europe, to a Genzyme facility in Waterford, Ireland.
- Third, get the Framingham Facility up and running for Fabrazyme® so that more of the available bioreactor space at the Allston Landing Facility could be dedicated to Cerezyme®.

167. Mr. Canute and his team had matters under control. Thus, in April 2010, Genzyme reported: "Genzyme has made progress in increasing the productivity of the Fabrazyme® manufacturing process [at the Allston Landing Facility and generally]. The first run of a new working cell bank ("WCB") resulted in a 30 percent increase in productivity, and a second run is underway. Genzyme's goal is to increase productivity an additional 30 percent."

168. Genzyme also made efforts to create an alternative method of manufacturing, known as continuous manufacturing, that would allow it to avoid throwing out an entire large batch of Fabrazyme® or Cerezyme® if one specification was missed.

169. By April 21, 2010, the Framingham Facility was physically complete. It was reported by Genzyme that:

> Across the company's manufacturing operations, programs to expand capacity are on-track. The new Framingham plant is mechanically complete. Pre-operational activities, including cell culture, media preparation, bioreactor validation and staff training, are currently taking place. Engineering and process validation runs are planned for this year.

Therefore, other than the pace and resources behind obtaining the requisite regulatory approvals, nothing was blocking resumption of full supply for both products.

170. As Genzyme reported in its Solicitation/Recommendation Statement on Schedule 14D-9 (the "14D-9 Filing") prior to the Sanofi merger:

> The Company has developed a new working cell bank for Fabrazyme that has been approved by the United States Food and Drug Administration ("FDA") and the European Medicines Agency. The new working cell bank has completed five runs and has had approximately 30% to 40% greater productivity than the prior working cell bank. Fabrazyme patients were able to begin doubling doses in the fourth quarter of 2010. The Company expects to fully supply global Fabrazyme demand for currently treated patients during the second half of 2011. The Company is also constructing a new manufacturing facility in Framingham, Massachusetts that will include four bioreactors that can be used for Cerezyme and Fabrazyme production. The Company expects to receive FDA approval for the new facility in the second half of 2011.

171. As is discussed more fully below, when Sanofi took over, it materially breached its obligations under the CVR Agreement by failing to provide the resources and set the pace that would have allowed for the resumption of full production and supply for both Fabrazyme® and Cerezyme®.

E. Sanofi approaches Genzyme about a possible merger buy out, touting its pharmaceutical manufacturing expertise.

172. During the week of June 28, 2010, Mr. Chris Viehbacher, CEO of Sanofi, called Mr. Henri Termeer, the Genzyme CEO, to convey Sanofi's interest in a potential acquisition of Genzyme.

173. On July 29, 2010, Mr. Viehbacher sent a letter to Mr. Termeer offering to acquire Genzyme. On September 20, 2010, Mr. Termeer and Mr. Viehbacher, along with other representatives of Sanofi and Genzyme, met to discuss Sanofi's offer. Mr. Viehbacher, making explicit reference to the risks inherent in the full resumption of supply of Fabrazyme® and Cerezyme®, emphasized that a deal was in the best interests of Genzyme's shareholders. Mr. Termeer demurred, noting his confidence in the resumption of supply for Fabrazyme® and Cerezyme®.

174. On October 5, 2010, after being provided information by Genzyme management, including the plans and probable outcomes for the recovery of Fabrazyme® and Cerezyme® production, both of Genzyme's financial advisors opined that Sanofi's offer was inadequate. A central component of those opinions was Sanofi's failure to fully consider how far along Genzyme was in its manufacturing recovery plans.

175. Starting as early as his initial pitch to Genzyme's shareholders, Viehbacher consistently took the position that an acquisition would create value because of the proven capabilities of Sanofi on the manufacturing front. Sanofi repeatedly portrayed itself as the balm that would solve all of Genzyme's manufacturing woes.

176. In August 2010, in announcing the hostile tender offer, Mr. Viehbacher stated that, at least with respect to "fill and finish, you're into a process that looks very much like what we do for vaccines and Lovenox and Lantus. So we have considerable capacities in those areas and considerable quality expertise there that we think actually could enhance not only fixing the manufacturing problems but also probably in terms of capacity utilization."

177. At the same event, Mr. Viehbacher also stated that: "To begin with, Sanofi-Aventis has a world-class manufacturing infrastructure and global quality organization.

Based on our analysis of Genzyme's situation, we are confident that we can bring additional sophisticated manufacturing expertise that will accelerate solutions to the manufacturing issues."

178. In September 2010, in answering a question as to whether Sanofi could help Genzyme with its manufacturing problems, Mr. Viehbacher answered in the affirmative. He pointed to Sanofi's expertise in producing bulk product, sterile fill and finish, rationalization of production, improving yield issues on cell banks, transferring knowledge gained from the production of Lovenox, monoclonal antibodies, and vaccines.

179. On October 4, 2010, in his letter to Genzyme, Mr. Viehbacher stated that "Sanofi-Aventis is well positioned to help Genzyme address its manufacturing problems" and claimed that this would de-risk the current situation for the Genzyme shareholders.

180. These statements set expectations for Sanofi's ability and willingness to assist in the manufacture of Fabrazyme® and Cerezyme®.

F. Sanofi and Genzyme merger is finalized, including the CVR Agreement, which requires Sanofi to pay Holders (former Genzyme shareholders) if certain post-merger Fabrazyme® and Cerezyme® production targets are met.

181. Though merger negotiations continued, Sanofi and Genzyme could not agree on the appropriate price. In November 2010, the companies and their legal and financial advisors began to discuss the possibility of a contingent value right (CVR) as a way to bridge the valuation gap.

182. Though initially only proposed as to Lemtrada®, the CVR was also applied to the production of Fabrazyme® and Cerezyme®.

183. On March 30, 2011, Sanofi and the Trustee executed the CVR Agreement. The CVRs created thereunder were subject to an express trust for the benefit of the Holders.

184. Pursuant to the CVR Agreement, Sanofi was obligated to make a Production Milestone Payment of $1.00 per CVR if the Production Milestone was met.

185. The CVR Agreement entitles Holders to receive $1.00 per CVR (or a total of almost $300 million, (not including interest) in the event that the production levels of Cerezyme® and Fabrazyme® hit the following thresholds by the end of calendar 2011: (a) production of at least 734,600 units of Cerezyme® (with each unit measured on a "400 Unit Vial Equivalents" basis) and (b) production of at least 79,000 units of Fabrazyme® (with each unit measured on a "35-milligram Vial Equivalents" basis).

186. Genzyme published to its shareholders and filed with the Securities and Exchange Commission a Schedule 14D-9 on March 7, 2011, which stated, based on estimates from its third-party financial advisors, that the Production Milestone had a 70% probability of attainment. Based, *inter alia*, on this projection, Genzyme recommended that its shareholders approve the merger.

187. The effective date of the CVR Agreement is March 30, 2011. That is, all of the obligations of the CVR Agreement due by Sanofi commenced no later than March 30, 2011, the date of the execution by Sanofi.

G. Under the CVR Agreement, Sanofi was required to use commercially reasonable efforts to reach the Production Milestone "on a timely basis."

188. In order to ensure that Sanofi would endeavor to meet the Production Milestone, Genzyme bargained for the following covenant: "The Company. . . shall use commercially reasonable efforts to achieve the Production Milestone on a timely basis."

189. The term "the Company" in the CVR Agreement refers solely and exclusively to Sanofi.

190. Thus, under the CVR Agreement, Sanofi itself would be responsible for the manufacture release of Fabrazyme® and Cerezyme®; it could not abdicate responsibility to others such as Genzyme.[11] Sanofi was required to take proactive, commercially reasonable efforts in a timely manner, for the express purpose of achieving the Production Milestone.

H. Sanofi delays implementing any required efforts at all, admitting halfway through the relevant period that it had not yet done work on Production Milestone manufacturing.

191. Even though, at least as early as February 2011, and certainly by March 2011, Sanofi had an obligation to take commercially reasonable efforts to do so, Sanofi took no initial steps to achieve the Production Milestone.

192. Sanofi did not make suggestions, provide technical expertise, take steps to maintain the projected timelines for improving the yield of production, transfer fill or finish, or get the Framingham Facility approved on a timely basis.

193. Until at least July 2011, Sanofi impermissibly relied exclusively upon Genzyme to discharge Sanofi's contractual obligation.

194. Sanofi's abdication of any action or responsibility, and therefore the breach of its contractual obligations, was admitted to by Sanofi's CEO in July 2011.

195. When asked about Sanofi's obligations with respect to the Production Milestone, Chris Viehbacher noted that "[w]ell, actually, it's all the Genzyme team that has been doing the manufacturing . . . ."

196. Sanofi's obligations under the CVR Agreement did not allow it to rely on Genzyme legacy programs with no efforts of its own to meet the Production Milestone.

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[11] As a result of the consent decree, all Release of Fabrazyme® and Cerezyme® from the Allston Landing Facility had to be approved by The Quantic Group. This did not, however, diminish Sanofi's obligation to manufacture those products.

197. Sanofi also does not have the excuse that it had to learn about Genzyme before stepping in. The Merger Agreement contemplated that prior to the closing of the merger, Sanofi would have access to relevant information concerning Genzyme, including, without limitation, information pertinent to the Production Milestone. Sanofi had done extensive diligence on Genzyme and its manufacturing of Fabrazyme® and Cerezyme®, and thus had the background knowledge necessary to begin to take the required efforts.

198. The merger had already been cleared by the relevant antitrust authorities and, as such, no applicable antitrust regulation prevented Sanofi and Genzyme from actively working together to reach the Production Milestone, even before the merger closed.

I. Sanofi oversaw catastrophic regime change and brain drain in the relevant Fabrazyme® and Cerezyme® production operations.

199. Sanofi also failed to take commercially reasonable efforts to prevent the crippling departure of employee talent and institutional knowledge that occurred following the merger, thereby harming its ability to meet the Production Milestone.

200. The resulting large scale employee departures caused a depletion of knowledge and talent from the manufacturing, process development, and relevant R&D centers. It also hurt morale among those who were retained. This negatively impacted the achievement of the Production Milestone.

201. As for those employees Sanofi wanted to retain, negotiations for retention bonuses were delayed. Negotiations did not start until at least April 2011 and many retention letters were still being negotiated in June 2011. Even when retention letters were executed, all that Sanofi offered was standard Sanofi stock options and not any incentives for the achievement of any of the Milestones in the CVR Agreement.

202. Sanofi implemented no incentive structures to keep critical employees who did not have their options vested as a result of the merger and took few steps to induce such employees to remain. Since many of the employees at the Allston Landing Facility and/or the Framingham Facility did not receive any CVRs after the merger, there was no incentive to work to meet the Production Milestone.

203. In July 2011, Mr. Canute's employment with Genzyme was terminated. In his place, Sanofi brought in former Sanofi executive Bill Aitchison. Mr. Aitchison previously headed Sanofi's vaccine production and had experience dealing with the FDA with respect to cGMP issues that had arisen at a Sanofi vaccine plant. There is no evidence that Mr. Canute was asked to continue through the December 31, 2011 Production Milestone date or otherwise stay and transition out of his position.

204. Integration planning between Genzyme and Sanofi did not commence until May 2011. As part of the integrations, Sanofi conceptualized a new reporting structure for manufacturing at Genzyme, implementing an additional level of reporting to Sanofi headquarters.

205. In truth, Sanofi was driving attrition at Genzyme in order to cut costs.

206. In order to obtain cost-saving synergies as a result of the merger to raise Sanofi's expected earnings per share, Sanofi had targets for the number of employees who would either leave or be fired. Sanofi planned to permit critical employees to leave and then to either hire more cost-efficient contractors or hire new employees once the Production Milestone passed.

207. Sanofi even publicly touted these cuts as "cost synergies." In a February 2012 press release, Sanofi noted that "[t]he $700 million targeted cost synergies [at Genzyme] by 2013 are on track and $230 million were already achieved in 2011."

208. The lack of experienced assistance was telling at Genzyme, and Sanofi's new head of manufacturing was not up to the task. Mr. Aitchison and the other Sanofi executives and employees brought in to oversee manufacturing did not understand the unique processes in place at Genzyme, the culture of the organization, and/or the specific needs of the products at issue. For example:

- Neither Mr. Aitchison nor any of the other Sanofi executives tasked with overseeing the resumption of manufacturing had offices either at the Allston Landing Facility or the Framingham Facility.

- Mr. Aitchison apparently had little experience dealing with The Quantic Group and did not insist that they be more frequently present at the Allston Landing Facility.

- Mr. Aitchison and his group did not have substantive experience with the commissioning, approval and permitting of a facility as complex as the Framingham Facility. Having not been part of the original discussions with the designers, engineers, regulatory consultants and regulatory agencies, this team had to catch up on information and this caused unnecessary delays and missed opportunities to accelerate the approval.

- Mr. Aitchison did not, as promised by Sanofi, appear to make any efforts to use any of the resources available at Sanofi to use commercially reasonable efforts to achieve the Production Milestone. There is no evidence that Sanofi sought to move production to another facility or bring technology known to be available to Sanofi to bear.

J. Sanofi had the capability to assist Genzyme with its bio-manufacturing needs in several substantive areas, but did not take required efforts to do so on a timely basis.

209. Sanofi had the expertise to ensure the Production Milestone was met. Sanofi had been active in developing its own capabilities in biomanufacturing. For example:

- Due to the rapid timelines necessary to develop a new flu vaccine every year and based on its experience in preparing for a rapid response to a pandemic influenza outbreak, Sanofi had developed, at least with respect to vaccines, sophisticated techniques for the rapid development of mammalian cell culture based production of proteins such as antigens or viruses. In September 2010, Pierre Fourier, associate vice president of manufacturing technology at Sanofi Pasteur, presentenced a keynote address at a conference on global vaccine production suggesting a high degree of expertise for rapid cell line development at Sanofi.

- Commencing in 2008, Sanofi had launched its KITE initiative. The initiative, which stood for Knowledge & Innovation for Technology Excellence, focused on improving Sanofi's capabilities including in the manufacture of biologics.

- In November 2009, Sanofi had acquired Shantha Biotechnics, an India based vaccine manufacturer that had been "focusing its R&D efforts in the development of generic biologicals, novel therapeutic antibodies, proteins and vaccines."

- In March 2009, Sanofi had announced the initiation of its BIOLAUNCH project at its Vitry-sur-Seine pharmaceutical production site. According to the press release "[w]ith BIOLAUNCH, Sanofi-Aventis will benefit from a complete platform of expertise in biotechnologies." CEO Chris Viehbacher noted that "[t]his project, which gathers and mobilizes the best expertise both inside and outside the company, is an illustration of the ongoing transformation program within Sanofi-Aventis."

- In July 2010, Biolex Therapeutics, Inc. and Merial Ltd., the animal vaccine subsidiary of Sanofi, entered into a research and development program relating to a proprietary biologics expression system. While focused on animal vaccines, the system had direct application to human vaccines and human proteins.

210. Sanofi's expertise was of particular significance in one area – single-use bioreactors. A single-use bioreactor is a disposable bioreactor that does not need to be cleaned or controlled between batches. One of the benefits of the technology is that it permits product to be brought up to production levels far more rapidly than a traditional stainless steel bioreactor. According to an industry publication, as of 2010, Sanofi had undertaken the evaluation of single-use bioreactors for the manufacture of biologics.

211. In fact, in July 2011, in the middle of the relevant period for the achievement of the Production Milestone, Jean-Marc Guillaume, Ph.D. – from Sanofi's Bioprocessing R&D facility in Marcy l'Étoile, France – reviewed how single-use bioreactors, as part of the KITE initiative, had been evaluated at Sanofi. Dr. Guillaume noted that these systems offer "[f]lexible production configurations [that] can provide for surge capacity needs." According to the presentation, a single-use bioreactor had the capacity, at least with respect to the upstream processes, to be fully operational in no less than sixty days. More importantly, due to their small size, they could be sited in existing cGMP facilities.

212. Sanofi also had expertise in the downstream portion of the biologics manufacturing process. Due to experience with parenteral and infusion drugs, Sanofi had vast technical experience with respect to specialized systems for inspection and quality control for fill and finish. For example, in November 2010, Joseph C. Frantz, Ph.D, presented on technology used at Sanofi Pasteur to visually inspect vials containing vaccines.

213. Genzyme itself also initiated several manufacturing improvement activities in 2010 and 2011 that later bore fruit, but were not fully implemented in time to achieve the Production Milestone due to a lack of required efforts by Sanofi after the merger.

214. For example, scientists in Genzyme's manufacturing and science and technology operations support group were developing a microcarrier perfusion culturing method for Fabrazyme® that provided "significant improvements in substantially improved cell density and protein production." Also, the addition of a reagent known to exist in 2011, Trace A by Invitrogen, was able to improve yield. However, Sanofi did not use commercially reasonable efforts to implement these known and available yield improvements to achieve the Production Milestone on a timely basis.

215. Other scientists known to be working at Genzyme's process development group in 2011 were working on an "integrated continuous biomanufacturing process for producing a therapeutic protein drug substance" that provided potential increases in efficiency and quality control in the biomanufacturing of Fabrazyme® and Cerezyme®. The continuous biomanufacturing process, however, was not pursued by Sanofi with commercially reasonable efforts on a timely basis in order to achieve the Production Milestone.

K. Finally, after barely even starting, Sanofi throws in the towel on achieving the Production Milestone five months before the deadline.

216. Sanofi announced mid-way through the Production Milestone time period that it would not reach the milestone, essentially giving up entirely on meeting its contractual obligation to use commercially reasonable efforts to do so.

217. In July 2011, Sanofi issued a press release predicting that the Production Milestone would not be met, but offered no insight as to what efforts it had taken or would use to rectify the situation. The press release states, in part:

> Genzyme continues to make progress at its Allston Landing manufacturing plant and the company is on track with requirements of the Consent Decree. The company will no longer perform fill/finish operations within the Allston facility, which is ahead of the August 31 Consent Decree deadline for products sold outside of the United States. Nevertheless, based upon actual production trends to date and lead times to release products for the market, Sanofi does not expect that the 2011 Contingent Value Right (NASDAQ: GCVRZ) Production Milestone will be met.

218. There is no evidence that Sanofi took any actions whatsoever after it projected that the current trend suggested that the level of production was not sufficient to achieve the Production Milestone.

219. In reality, the actual difference between what ultimately was produced and what was required for the Production Milestone was only thirty percent (30%), casting serious doubt on the data and motivations behind Sanofi's July 2011 declaration.

220. By the end of January 2012, the Framingham Facility (at which Cerezyme® and Fabrazyme® were manufactured) was approved by the FDA, and normal supplies of Fabrazyme® were expected by the second quarter of 2012.

221. Sanofi was also able to reach and surpass the production level required by the Production Milestone within just three months of the missed December 31, 2011 deadline.

222. Had Sanofi undertaken the bare minimum of its contractually required efforts, the Production Milestone would have been timely met. That Sanofi was able to resume full supply and then some by the middle of 2012 suggests that there was no inherent reason that the level of supply was fundamentally unachievable by the December 31, 2011 deadline other than to evade its payment obligation under the CVR Agreement.

223. One explanation given by Sanofi for its failure to achieve the Production Milestone was that the transfer of Fabrazyme® production to the Framingham Facility was not expected to be complete until the first quarter of 2012. But this was a result of Sanofi's own failure to use commercially reasonable efforts to achieve the Production Milestone.

224. The primary reason given for why production was not transferred over was because of a delay in initiating three validation runs in order to obtain pre-approval. But the timing of the initiation of the validation run was entirely within Sanofi's control as of April 2011. It was not until November 2011 that Sanofi management noted that all that had to happen was that the facility had to "produce three validation lots, all of which has to be approved, and then [have the] site [ ] inspected." As of that date it was noted that "[w]e've had some ongoing inspections of the site, as we've been producing validation lots. And those have gone very well."

225. In addition, the approval could have been obtained without the validation runs, or, alternatively, the runs could have been made and included as commercial stock.

226. Even without taking additional steps, modest efforts could have accelerated the approval of the Framingham Facility. The delay in the Framingham Facility until 2012 was unnecessary and was caused by inadvertent and/or intentional delays in validating the bioreactors at the facility. This delay meant that the Allston Landing Facility was delayed in switching over to Cerezyme®-only production.

227. A second excuse given by Sanofi for the failed Production Milestone involved the yields of production. However, as explained above, it was not only possible but likely that yields could have been improved had more attention and resources been allocated.

228. Many different potential routes to increasing production, including accelerating fill and finish, were available to Sanofi. These included using disposable bioreactors or engaging in technology transfer to a contract manufacturing organization and/or use of alternative production approaches. Each of these alternatives are standard in the industry. Had Sanofi exercised commercially reasonable efforts, the Production Milestone would have been timely met.

VII. Sanofi Has Breached and Is Continuing to Breach Sections 4.2(f) and 5.4(b) of the CVR Agreement

Request regarding the Production Milestone

229. On December 9, 2016, the Trustee made a request to Sanofi pursuant to Sections 4.2(f) and 5.4(b) of the CVR Agreement to investigate whether Sanofi complied with the covenant in the CVR Agreement concerning the Production Milestone. A true and correct copy of the December 9, 2016 request is attached as Exhibit D.

230. In connection with the Trustee's request to Sanofi, the Trustee sought documents and reports necessary to complete the investigation. The Trustee also requested that Sanofi confirm that it would reimburse the Trustee for its costs and expenses incurred in

connection with the investigation as Sanofi is required to do under Section 4.2(f) of the CVR Agreement.

231. On January 12, 2017, Sanofi responded to the Trustee's December 9, 2016 request. Through counsel, Sanofi stated that it would not cooperate with the Trustee's investigation concerning the Production Milestone or reimburse the Trustee for its costs and expenses in connection therewith. A true and correct copy of Sanofi's January 12, 2017 letter is attached as Exhibit E.

232. Sanofi's refusal to cooperate with the Trustee's investigation into the Production Milestone is a material breach of Sanofi's obligations under Section 4.2(f) of the CVR Agreement to allow the Trustee to "examine the books, records and premises of the Company, personally or by agent or attorney, as necessary" as requested by the Trustee.

233. Sanofi's refusal to cooperate with the Trustee's investigation concerning the Production Milestone is a material breach of Sanofi's obligations under Section 5.4(b) of the CVR Agreement to "file with the Trustee such additional information, documents and reports with respect to compliance by the Company with the conditions and covenants of this CVR Agreement as may be required from time to time by the Trustee."

234. Sanofi's refusal to reimburse Trustee for its costs and expenses in connection with its investigation concerning the Production Milestone is a material breach of Sanofi's obligations under Section 4.2(f) of the CVR Agreement to conduct investigations requested by the Trustee "at the sole cost of the Company [*i.e.*, Sanofi]."

Request regarding Product Sales Milestones #2 through #4

235. The CVR Agreement also requires Sanofi to continue to take Diligent

Efforts to meet Product Sales Milestones #2 through #4.[12]

236. If Sanofi meets the Product Sales Milestones #2 through #4, Sanofi will owe Product Sales Milestones Payments to Holders in the following amounts:

- Product Sales Milestone #2 – four dollars ($4.00) per CVR;
- Product Sales Milestone #3 – four dollars ($4.00) per CVR; and
- Product Sales Milestone #4 – three dollars ($3.00) per CVR.

237. On December 15, 2016, the Trustee made a request to Sanofi pursuant to Sections 4.2(f) and 5.4(b) of the CVR Agreement to investigate whether Sanofi's current conduct was consistent with its Diligent Efforts obligations under the CVR Agreement to achieve Product Sales Milestones #2 through #4. A true and correct copy of the December 15, 2016 request is attached as Exhibit F.

238. In connection with the Trustee's request to Sanofi, the Trustee sought documents and reports necessary to complete the investigation. The Trustee also requested that Sanofi confirm that it would reimburse the Trustee for its costs and expenses incurred in connection with the investigation as Sanofi is required to do under Section 4.2(f) of the CVR Agreement.

239. On January 12, 2017, Sanofi responded to the Trustee's December 15, 2016 request. Through counsel, Sanofi stated that it would not cooperate with the Trustee's investigation concerning Product Sales Milestones #2 through #4 or reimburse the Trustee for its costs and expenses in connection therewith. A true and correct copy of Sanofi's January 12, 2017 letter is attached as Exhibit E.

[12] The Court has concluded that, "[t]o the extent that Plaintiff argues that the Complaint sufficiently alleges a breach of contract based on PSM #2-4, this Court disagrees, as the deadline to meet those milestones is not until December 31, 2020." Memorandum Decision and Order (ECF No. 76), at 12 n.6.

240. Sanofi's refusal to cooperate with the Trustee's requested investigation concerning Product Sales Milestones #2 through #4 is a material breach of Sanofi's obligations under Section 4.2(f) of the CVR Agreement to allow the Trustee to "examine the books, records and premises of the Company, personally or by agent or attorney, as necessary" as requested by the Trustee.

241. Sanofi's refusal to cooperate with the Trustee's investigation concerning Product Sales Milestones #2 through #4 is a material breach of Sanofi's duty under Section 5.4(b) of the CVR Agreement to "file with the Trustee such additional information, documents and reports with respect to compliance by the Company with the conditions and covenants of this CVR Agreement as may be required from time to time by the Trustee."

242. Sanofi's refusal to reimburse Trustee for its costs and expenses in connection with its investigation concerning Product Sales Milestones #2 through #4 is a material breach of Sanofi's obligations under Section 4.2(f) of the CVR Agreement to conduct investigations requested by the Trustee "at the sole cost of the Company."

VIII. Sanofi Breached Section 7.6(a) of the CVR Agreement

243. A group of Acting Holders requested that the Trustee submit a written request to Sanofi to submit to an independent audit pursuant to Section 7.6(a).

244. On December 19, 2016, the Trustee made a written request to Sanofi to submit to an independent audit of its Product Sales Statements and the figures set forth therein for the period from the first date upon which gross sales for the Product[13] were booked through

[13] "Product" is defined in the CVR Agreement as follows: "any of: (a) the humanized antibody directed against CD52 known as alemtuzumab; (b) any molecule which comprises alemtuzumab or a fragment, variant or derivative thereof that retains the ability to bind human CD52; (c) any other CD52-binding molecule having a structure and activity similar enough to the molecules described in clauses (a) or (b) of this definition to be classified as a biosimilar (or follow-on biologic or subsequent entry biologic or the like) thereof; and (d) any product containing any of the items described in clauses (a)-(c) of this definition as an active ingredient, in each case regardless of formulation, delivery system, or dosage form, provided that, notwithstanding the foregoing, any unit of

December 31, 2016. A true and correct copy of the December 19, 2016 request is attached as Exhibit G.

245. On January 12, 2017, Sanofi responded to the December 19, 2016 audit request. Through counsel, Sanofi stated that it would not cooperate with the audit request or pay the associated expenses. A true and correct copy of Sanofi's January 12, 2017 letter is attached as Exhibit E.

246. Sanofi's refusal to cooperate with the audit request is a material breach of its obligations under Section 7.6(a) of the CVR Agreement to allow an independent accounting firm to audit the Product Sales Statements and to pay for such audits.

247. Without an independent audit, the Acting Holders and Trustee are unable to fully assess the accuracy of Sanofi's Product Sales Statements and Sanofi's satisfaction of its obligations to make any Product Sales Milestone Payments.

CAUSES OF ACTION

COUNT I

BREACH OF CONTRACT FOR FAILURE TO USE DILIGENT EFFORTS TO MEET THE APPROVAL MILESTONE

248. Plaintiff repeats and re-alleges the facts set forth in paragraphs 1 through 247 herein as if set forth here in full.

249. Section 7.10 of the CVR Agreement requires Sanofi to use Diligent Efforts, including causing its Affiliate, Genzyme, to take certain actions, to achieve the Approval Milestone for Lemtrada®.

Product, to the extent sold for use in (i) oncology or (ii) Transplant Indications, in each of cases (i) and (ii) under the Campath® or MabCampath® trademarks, shall not be deemed to be 'Product' for the purposes of this CVR Agreement." CVR Agreement § 1.1.

250. Sanofi failed to use Diligent Efforts to achieve the Approval Milestone by submitting or causing Genzyme to submit an inadequate Application for FDA approval of Lemtrada® that failed to address the FDA's repeated concerns and requests for information regarding aspects of the Phase III trial design and results.

251. As a result of Sanofi's material breach, the Approval Milestone was not met and Sanofi did not pay to the Trustee, for the benefit of the Holders, the Approval Milestone Payment. Therefore, the Trustee, as trustee of an express trust for the benefit of the Holders, has suffered substantial damages.

COUNT II

BREACH OF CONTRACT FOR FAILURE TO USE DILIGENT EFFORTS TO MEET THE PRODUCT SALES MILESTONES

252. Plaintiff repeats and re-alleges the facts set forth in paragraphs 1 through 247 herein as if set forth here in full.

253. Section 7.10 of the CVR Agreement requires Sanofi to use Diligent Efforts, including causing its Affiliate, Genzyme, to take certain actions, to achieve the Product Sales Milestones for Lemtrada®.

254. Sanofi failed to use Diligent Efforts to meet Product Sales Milestone #1, thereby materially breaching the CVR Agreement by, among other things:

a. Failing to develop an appropriate REMS program and failing to seek to reduce the risk of side effects of Lemtrada®. These failures led the FDA to limit Lemtrada®'s use to a third-line therapy, thereby harming the Holders' prospects for reaching the Product Sales Milestones;

b. Failing to use the efforts or employ the resources normally used by companies in the pharmaceutical business to operate timely and meaningfully in major markets; and

c. Treating the achievement of Milestones and the contingent payments to Bayer as an expense and a reduction in profitability for Lemtrada®.

255. As a result of Sanofi's material breach, the Product Sales Milestones have not been met and Sanofi has not paid to the Trustee, for the benefit of the Holders, any of the Product Sales Milestone Payments. Therefore, the Trustee, as trustee of an express trust for the benefit of the Holders, has suffered substantial damages.

COUNT III

BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

256. Plaintiff repeats and re-alleges the facts set forth in paragraphs 1 through 247 herein as if set forth here in full.

257. Sanofi breached the implied covenant of good faith and fair dealing in the CVR Agreement by delaying Lemtrada® sales and keeping Lemtrada® sales volume low, which has depressed the trading price of the CVRs.

258. Sanofi's actions or inaction have been taken in bad faith to maximize Sanofi's opportunity to exercise the Failure Purchase option.

259. Sanofi's bad faith has stripped, and will strip, the Trustee, as trustee of an express trust for the benefit of the Holders, of the benefit of its bargain.

COUNT IV

DECLARATORY JUDGMENT AGAINST SANOFI REQUIRING REIMBURSEMENT OF TRUSTEE FEES AND EXPENSES

260. As set forth in the Trustee's Supplemental Complaint (ECF No. 52) (*see* footnote 1, *supra*), Plaintiff is seeking a declaratory judgment from this Court that the CVR Agreement obligates Sanofi to pay the Trustee's reasonable attorneys' fees, disbursements, and expenses incurred in investigating and prosecuting the claims brought in the Action, costs of distribution of notices pursuant to the CVR Agreement, and any other of the Trustee's expenses upon request or demand, all of which are continuing to accrue without payment by Sanofi.

COUNT V

DECLARATORY JUDGMENT AGAINST SANOFI FOR FAILURE TO COMPLY WITH TRUSTEE'S REQUESTS PURSUANT TO SECTIONS 4.2(f) AND 5.4(b) OF THE CVR AGREEMENT

261. Plaintiff repeats and re-alleges the facts set forth in paragraphs 1 through 247 herein as if set forth here in full.

262. Section 4.2(f) of the CVR Agreement provides that the Trustee may, in its sole discretion, initiate investigations into Sanofi's compliance with its obligations under the CVR Agreement. Section 5.4(b) of the CVR Agreement provides that the Trustee may, in its sole discretion, request reports from Sanofi concerning its obligations under the CVR Agreement. The CVR Agreement provides that Sanofi is obligated to pay for all of the Trustee's expenses incurred with respect to requests under both sections.

263. On December 9, 2016 and on December 15, 2016, the Trustee made requests pursuant to Sections 4.2(f) and 5.4(b) of the CVR Agreement for documents and reports to investigate Sanofi's compliance with certain of its covenants in the CVR Agreement.

264. On January 12, 2017, Sanofi responded to the Trustee's December 9, 2016 and December 15, 2016 requests. Sanofi stated that it would not cooperate with the Trustee's investigation requests or reimburse the Trustee for its costs and expenses in connection therewith. A true and correct copy of Sanofi's January 12, 2017 letter is attached as Exhibit E.

265. Sanofi's refusal to cooperate with the Trustee's investigation requests is a material breach of the express terms of the CVR Agreement.

266. As a result of Sanofi's refusal, the Trustee is unable to fully evaluate Sanofi's compliance with its covenants contained in the CVR Agreement.

267. An actual, present, and justiciable controversy exists between and among the Trustee and Sanofi.

268. The Trustee seeks a declaratory judgment from this Court that the CVR Agreement obligates Sanofi to cooperate with the Trustee's December 9, 2016 and December 15, 2016 investigation requests and to pay the Trustee's expenses associated therewith.

COUNT VI

DECLARATORY JUDGMENT AGAINST SANOFI FOR FAILURE TO COMPLY WITH THE TRUSTEE'S REQUEST, ON BEHALF OF ACTING HOLDERS, PURSUANT TO SECTION 7.6(a) OF THE CVR AGREEMENT

269. Plaintiff repeats and re-alleges the facts set forth in paragraphs 1 through 247 herein as if set forth here in full.

270. Section 7.6(a) of the CVR Agreement requires that Sanofi pay for an independent audit at the request of Acting Holders audits to verify the accuracy of its Product Sales Statements.

271. On December 19, 2016, at the request of Acting Holders, the Trustee made a written request to Sanofi to submit to an independent audit pursuant to section 7.6(a). A true and correct copy of the December 19, 2016 request is attached as Exhibit G.

272. On January 12, 2017, Sanofi responded to the December 19, 2016 audit request. Through counsel, Sanofi stated that it would not cooperate with the audit request or pay the associated expenses. A true and correct copy of Sanofi's January 12, 2017 letter is attached as Exhibit E.

273. Sanofi's refusal to cooperate with the Acting Holders' and the Trustee's December 19, 2016 request is a material breach of the express terms of the CVR Agreement.

274. As a result of Sanofi's refusal, the Acting Holders and the Trustee are unable to fully evaluate whether Sanofi owes any Product Sales Milestone Payments to Holders based on actual sales.

275. An actual, present, and justiciable controversy exists between and among the Trustee and Sanofi.

276. The Trustee seeks a declaratory judgment from this Court that the CVR Agreement obligates Sanofi to cooperate with the Acting Holders and Trustee's December 19, 2016 request and to pay the costs of the requested audit.

COUNT VII

BREACH OF CONTRACT FOR FAILURE TO USE COMMERCIALLY REASONABLE EFFORTS TO MEET THE PRODUCTION MILESTONE ON A TIMELY BASIS

277. Plaintiff repeats and re-alleges the facts set forth in paragraphs 1 through 247 herein as if set forth here in full.

278. Section 7.10 of the CVR Agreement requires Sanofi to use commercially reasonable efforts to achieve the Production Milestone for Cerezyme® and Fabrazyme® on a timely basis.

279. Sanofi materially breached the CVR Agreement by its failure to use commercially reasonable efforts to achieve the Production Milestone for Cerezyme® and Fabrazyme® on a timely basis, thereby materially breaching the CVR Agreement by, among other things:

a. Failing to take commercially reasonable efforts to accelerate or maintain the projected timelines to improve the yield of production of Cerezyme® and Fabrazyme® or to remedy fill and finish problems;

b. Failing to promptly deploy Sanofi resources to improve the yield of production of Cerezyme® and Fabrazyme® or to remedy fill and finish problems;

c. Failure to obtain timely approval of the Framingham Facility;

d. Interfering in the remediation plan put in place by Genzyme in detrimental ways;

e. Failing to retain important Genzyme employees after the merger, provide retained employees with adequate incentives to meet the Production Milestone, or to address the loss of knowledge and the impact of the merger on employee morale; and

f. Announcing in July 2011, five months before the Production Milestone deadline, that it would not meet the Production Milestone, and not engaging in commercially reasonable efforts thereafter to meet the Production Milestone.

280. As a result of Sanofi's material breach, the Production Milestone was not met and Sanofi did not pay to the Trustee, for the benefit of the Holders, the Production

Milestone Payment. Therefore, the Trustee, as trustee of an express trust for the benefit of the Holders, has suffered substantial damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court grant the following relief:

A. On Count I, a judgment that Sanofi materially breached its agreement with the Trustee with respect to the Approval Milestone and the Trustee, on behalf of the express trust for the benefit of the Holders, is entitled to an award of money damages of $1.00 per CVR, in an aggregate amount to be determined at trial, plus pre-judgment interest at the rate provided for in the CVR Agreement and costs, including all reasonable attorneys' fees and expenses as provided for in the CVR Agreement;

B. On Count II, a judgment that Sanofi materially breached its agreement with the Trustee with respect to the Product Sales Milestones and the Trustee, on behalf of the express trust for the benefit of the Holders, is entitled to an award of money damages in an aggregate amount to be determined at trial, plus pre-judgment interest at the rate provided for in the CVR Agreement and costs, including all reasonable attorneys' fees and expenses as provided for in the CVR Agreement;

C. On Count III, a judgment that Sanofi violated the covenant of good faith and fair dealing implied in its CVR Agreement with the Trustee and, therefore, the Trustee, on behalf of the express trust for the benefit of the Holders, is entitled to an injunction prohibiting Sanofi from exercising the Failure Purchase option and

money damages in an amount to be determined at trial, including reasonable attorneys' fees and expenses as provided for in the CVR Agreement;

D. On Count IV, a judgment declaring that the CVR Agreement obligates Sanofi to pay the Trustee's reasonable attorneys' fees, disbursements, and expenses incurred in investigating and prosecuting the claims brought in the above-captioned action, costs of distribution of notices pursuant to the CVR Agreement, and any other of the Trustee's expenses (as set forth in Respondents' Supplemental Complaint (ECF No. 52);

E. On Count V, a judgment from this Court declaring that that the CVR Agreement obligates Sanofi to cooperate with the Trustee's December 9, 2016 and December 15, 2016 investigation requests and ordering the performance of those obligations, including the payment of the Trustee's fees and expenses associated therewith;

F. On Count VI, a judgment from this Court declaring that that the CVR Agreement obligates Sanofi to cooperate with the Acting Holders and Trustee's December 19, 2016 audit request and ordering the performance of those obligations, including the payment of the costs of the requested audit;

G. On Count VII, a judgment that Sanofi materially breached its agreement with the Trustee with respect to the Production Milestone and that the Trustee, on behalf of the express trust for the benefit of the Holders, is entitled to an award of money damages of $1.00 per CVR, in an aggregate amount to be determined at trial, plus pre-judgment interest at the rate provided for in the CVR Agreement and costs, including all reasonable attorneys' fees and expenses as provided for in the CVR Agreement; and

H. Any such other and further relief as the Court may deem just, equitable, and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands trial by jury in this action of all issues so triable.

Dated: August 29, 2017
New York, NY

CAHILL GORDON & REINDEL LLP

By: /s/ Charles A. Gilman

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